EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-M-02327
MDL No. 2327
General re: PROLIFT matter

THIS DOCUMENT RELATES TO ALL WAVE 4 AND SUBSEQUENT WAVES CASES AND PLAINTIFFS:

Lisa Flowers
Case No. 2:12-cv-03922
Claudine Paul
Case NO. 2:12-cv-04808

Betty Thornton
Case No. 2:12-cv-05115

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DEPOSITION OF STEVEN GOLDWASSER, M.D.
PURSUANT TO NOTICE OF DEPOSITION

Taken on Behalf of the Plaintiffs

DATE TAKEN: March 29, 2017
TIME: 8:37 a.m. - 12:19 p.m.
PLACE: Courtyard Marriott Jacksonville Flagler Center
14402 Old St. Augustine Road
Jacksonville, FL 32258

Examination of the witness taken before:
Stephanie Powers Cusimano
Registered Professional Reporter
GOLKOW TECHNOLOGIES, INC.
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APPEARANCES

GREGORY D. BENTLEY, ESQUIRE
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Appearing on behalf of Plaintiffs.

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Appearing on behalf of Defendant.

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EXHIBITS

STIPULATION

It was stipulated and agreed by and between counsel for the respective parties, and the witness, that the reading and signing of the deposition by the witness not be waived.

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STEVEN GOLDWASSER, M.D., having been produced and first duly sworn as a witness, having responded, "I do," testified as follows:

DIRECT EXAMINATION

BY MR. BENTLEY:

Q Good morning, Dr. Goldwasser. My name is Greg Bentley. We met briefly off the record. Do you understand that we're here today to take your deposition for the plaintiffs in the Ethicon MDL?

A Yes.

Q And this is regarding your PROLIFT opinions; is that correct?

A Correct.

Q I'm handing you what's being marked as Exhibit 1, and this is a deposition notice for today. Have you seen that before?

(Exhibit 1 was marked for identification.)

A No.

Q If you'd look -- the first page is really just a legal document instructing you of the time and place, which we're here, so you made that, but there's some document requests at the back, I think it's in Exhibit A. If you'd turn to that, please. You with me?

A I'm getting there.

Q And I guess just a little bit of background. Doctor, have you been deposed before?

A Yes.

Q So you're probably familiar with the rules, but just so we're clear, when I ask a question, if you don't understand it, please let me know. And if you answer the question, I'm going to assume that you understood it; is that fair?

A Correct.

Q And is there any reason why you can't testify truthfully and accurately today?

A No.

Q And you understand that you're here today to testify under oath like you're in front of a jury or a judge?

A Correct.

Q And so turning back to Exhibit 1, are you -- I think the document request's on Exhibit A?

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A Yes.
Q And I think you said you didn't necessarily review this document, but were you asked to look for any documents in preparation for this deposition?
MR. RUMANEK: And let me just note on the record, I mean, I don't want you to -- I'll say on the record we've gone through it. I don't know whether he remembers seeing it or not.
MR. BENTLEY: Sure.
MR. RUMANEK: And we've brought some documents --
MR. BENTLEY: Right.
MR. RUMANEK: -- to the deposition, so I don't know if you want to identify those on the record or if you want to go through it with him, whatever --
MR. BENTLEY: We can go through it in a second and clean up.
BY MR. BENTLEY:
Q Let's just briefly look at the categories, Doctor. If I could see Exhibit 1 real fast. I didn't bring another copy.
All right. So the first item is a CV, which I think you provided that to us; is that

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correct?
A Correct.
Q And have you updated your CV since you provided it to us?
A I don't believe so.
Q And then item 2 is, "Any documents in your possession, which you created or you have relating to your opinions in this litigation." Do any of those documents exist or have you produced them?
A Repeat that one more time.
Q Have you created any documents in preparation for --
A Oh, no, no.
MR. RUMANEK: Well, let me -- he's created a report. I don't know what --
Q Right. In addition to the report and to the -- obviously the literature cited, which I assume is in that binder, have you done any other type of analysis, summaries, reports in preparation for developing your opinions here?
A Nothing written.
Q And you have a binder in front of you, is that the literature that you cited in your report?
A Correct.
Q In addition, you reviewed some other

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documents, as indicated on your reliance list, which we'll look at in a little bit. Are all the documents you reviewed on your reliance list?
A Correct.
Q And you didn't bring any of the documents you reviewed to the deposition today?
MR. RUMANEK: Object to the form.
A Any documents -- can you repeat that one more time?
Q Did you bring any of the other documents except for the stuff in that binder?
MR. RUMANEK: (Indicating.)
MR. BENTLEY: Counsel is showing me a flash drive.
MR. RUMANEK: Yes, so we have a flash drive that is noted as Goldwasser General Materials, which has, I believe, everything that's on his reliance list --
MR. BENTLEY: Okay.
MR. RUMANEK: -- certainly what was provided to him.
MR. BENTLEY: Good.
BY MR. BENTLEY:
Q Do you have any Ethicon products in your possession?

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A No.
Q Did you bring with you to the deposition time sheets, invoices, things like that?
A No.
Q Did you bring copies of any consulting agreements or reports you provided to Ethicon as a consultant?
A No, only this --
Q Just the literature?
A -- general report.
Q Did you bring any information regarding studies you've done or your case log or data analyses?
A Yeah, I do have an abstract of some --
Q Other than that you didn't bring any other --
A Correct.
Q And do you have other -- obviously other information regarding your case log and analyses and abstract and that such?
MR. RUMANEK: Object to the form.
A I do have an ongoing database --
Q Right.
A -- but I don't have it with me.
Q And do you have summary reports that you

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keep, or what type of analysis do you have?
A Just what's in the abstracts presented.
Q And who does the statistical analysis of your case log?
A I couldn't tell you exactly.
Q You don't do it personally?
A Correct.
Q When have you been deposed before, Doctor?
A I was deposed, I believe, sometime in 2016.
Q And is that the only time you've been deposed prior to today?
A I think I was deposed one time prior, but I couldn't tell you exactly.
Q Let's start with the first time, what was the context of that deposition?
A You mean in 2016?
Q Sure.
A That was regarding product liability. I was deposed as an expert witness.
Q And was that involving a mesh product?
A I believe it was.
Q And were you hired as a defense expert witness?
A I was -- I'm trying to think. Yes. Well,

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I actually treated the patient, so I was there in that context.
Q So, you know, it's a legal distinction, I'm not sure -- I think you probably would understand. You know, if you're testifying as a fact witness regarding your treatment of a patient, that would be considered a fact witness versus today you're here as an expert for the defendant, Ethicon; is that correct?
A Correct.
Q And so in 2016 when you were deposed, what was the context of your -- of your role in that deposition?
A I believe I was a -- well, I couldn't tell you exactly. I don't recall.
MR. RUMANEK: I think it was in the context of him as an implanting physician.
Q Okay. What --
A Actually I was a treating -- I think I was treating.
Q Right.
A I think I --
MR. RUMANEK: Yes, it was as a fact witness.
MR. BENTLEY: Got you. Got you.

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Q And what product was in that -- was that deposition concerning?
A You know, I don't recall whether it was Bard or Ethicon, I don't recall.
Q So other than that deposition, have you been deposed any other times in your career?
A There was one other one in 2016, same circumstances.
Q Okay.
A And prior to that, I couldn't tell you exactly, I don't remember.
Q Have you worked as an expert witness in -- any other time besides in this litigation today?
A No.
Q Have you ever testified at trial?
A No.
Q Are you excited to testify at trial?
A Oh, sure.
Q So let's talk about -- a little bit about your preparation for today. When did you start working on your opinions in this case?
A I believe it was, let's see, probably the end of 2016. I don't remember exactly which month, but sometime right around there.
Q And since we don't have the invoices, I'm

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going to go into this a little bit, approximately how much time did you spend preparing your report?
A Preparing the report, I couldn't tell you exactly. Probably at least 20 hours, possibly more.
Q And have you billed for that time yet?
A No.
Q When do you anticipate billing for that time?
A At the end of the closing of this wave of cases.
Q You currently have time sheets recording how much time you spent on that report?
A Correct.
Q When did you start preparing for this deposition?
MR. RUMANEK: Object to the form.
A Probably about two or three weeks ago. Originally it was scheduled and canceled and rescheduled. It's probably about three weeks ago.
Q And did you meet with Counsel in preparation for this deposition?
A Correct.
Q How many times did you meet?
A Twice.
Q And how long were those two meetings?

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A The first meeting was probably like around six or seven hours, and the second meeting was around four or five hours. Probably about four hours.
Q And in addition to those meetings with Counsel, did you do any preparation on your own for the deposition today?
A Correct.
Q And how much time did you spend preparing on your own?
A Probably about 15 hours.
Q Did you review materials in preparation for today?
A Correct.
Q Did you review any materials in addition to that which is cited in your report and listed on your reliance list?
A I don't believe so.
MR. RUMANEK: Let me just clarify because I'm not 100 percent sure. I think we did -- he did look at his abstracts, which he's brought with him, and I'm not certain if those are specifically on the reliance list.
MR. BENTLEY: Okay.
Q Doctor, let me hand you what's being

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marked as Exhibit 2, which I believe is a copy of your CV. Does that look correct?
(Exhibit 2 was marked for identification.)
A Correct.
Q And does this contain a complete and accurate list of your education and experience and publications and such?
MR. RUMANEK: Object to form.
A To the best of my recollection, correct.
Q As you sit here today, do you have any items that you need to add that you're aware of?
A No.
Q And let's just briefly go over your education. Where did you go to school, Doctor?
A For undergraduate?
Q Yeah.
A University of California, San Diego.
Q And then for med school?
A Tulane.
Q Tulane. And then you did a fellowship under Mickey Karram?
A Correct.
Q Do you still keep in touch with Mickey?
A From time to time.
Q And I noticed you did a -- you published

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with Dr. Karram?
A Correct.
Q On the last page of your CV, which is marked as Exhibit 2, you have a section called Inventions; do you see that?
A Correct.
Q And what device are you describing there?
A This -- well --
MR. RUMANEK: Object to form. To -- are you asking about the first one, the second one, or both?
Q Or are they the same device you're talking --
A No, they are two separate devices.
Q So what are the devices that you're talking about?
A So the first one is regarding a product called Ex- -- which actually came to be known as Exair, which is a mesh-based product for the treatment of prolapse, and the second one is a surgical retractor.
Q So let's talk about the first one. It's a -- you helped design a product called Exair?
A Exair, correct.
Q And who did you work on designing that

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product with?
MR. RUMANEK: Object to the form.
A A colleague of mine, another physician.
Q And was that product eventually brought to market?
A Correct.
Q And who marketed that product?
A Coloplast.
Q And was that for the treatment of prolapse?
A Correct.
Q And it was a polypropylene-based product?
A Correct.
Q And what was your involvement in designing that product?
A Technique. Bas- -- mainly technique based.
Q You didn't actually like design the mesh itself?
A Correct.
Q Did you design maybe the inserters or -- I'm just trying to flush out what you actually did on that imaging.
A My role was the actual technique itself for implant of the mesh, and the actual mesh itself

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was -- was a product that Coloplast owned. The inserters were developed by the engineers over there.
Q And did you assist in the development of marketing materials for that product?
A No.
Q Did you assist in developing professional education materials for that product?
A I don't believe so directly.
Q Would -- did you assist in the regulatory submissions for getting approval for that product?
A No.
MR. RUMANEK: Object to the form.
Q Did you assist in drafting the IFU for that product?
A I believe I was involved in reviewing it but not directly hands on writing it.
Q Would you have been involved in writing the procedural aspects of the IFU maybe?
A I believe so.
Q Do you remember if you were involved in writing the Adverse Reaction section?
MR. RUMANEK: Object to the form.
A No.
Q I'm sorry, no, you don't remember or no,

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you weren't involved in that?
A I don't think I was -- I don't think I was involved.
Q Is that product still on the market today?
A No.
Q Did you have a financial interest in that product?
A Just in the development consultation base.
Q It was an hourly?
A Correct.
Q So if I saw some documents to indicate you had a financial interest, that wouldn't be correct?
MR. RUMANEK: Object to the form.
A Only as a consultant, correct.
Q When you were designing that product, I would assume you supported and you thought what you were doing was useful, right?
A Correct.
Q Did you -- did you think that the finished product you helped design was a safe and effective device to be used?
A Yes.
Q And did you end up using that device once it came on the market?
A Correct.

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Q I think I've seen you previously worked as a preceptor for Ethicon; is that correct?
A Correct.
Q And when did you first -- or what is a preceptor?
A A preceptor is a -- well, I was actually involved more so not -- I don't believe I was demonstrating the procedure on patients in the hospital with people visiting, I believe I was the instructor for cadavers and reviewing the technique.
Q And what products were you demonstrating technique for on cadavers?
A I believe it was the retropubic TBT and the PROLIFT device.
Q When do you think you were teaching on the TBT retropubic?
A At the -- I believe it was the same time as the PROLIFT device. I couldn't tell you the exact year, but they overlap.
Q Well, because -- do you have an understanding that PROLIFT came on the market around 2005?
A Correct.
Q So you think that you didn't -- you weren't teaching TBT until around 2005?

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MR. RUMANEK: Object to the form.
A You know, I don't recall whether I did some separate things for them prior to that.
Q When did you first begin using mesh products in your practice?
A Probably early 2000s, prior to 2005.
Q And would you have first used the mesh -- a mesh product, like a mid urethral sling, to treat incontinence?
A Oh, no -- okay. The first question was on prolapse, you said?
Q Just generally --
A General.
Q -- when did you -- I'm trying to see when your experience began with mesh.
A So first experience would be retropubic slings in '98.
Q And before that did you use any non-polypropylene mesh products?
MR. RUMANEK: Object to the form.
A Not that I recall.
Q And then around '98 when TBT classic came to market, you began using it to treat women with incontinence; is that correct?
A Correct.

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Q And then subsequent to that, you began using a mesh-based product to treat women that's suffering from prolapse; is that correct?
A Correct.
Q And that -- what would have been the first product that you used whether it was a polypropylene-mesh-based product for prolapse treatment?
A Probably -- it was either a Bard product or Gynemesh, one of the two.
Q Okay.
A I don't remember which I was using first.
Q Are those the -- have you used products from any other manufacturers besides Bard and Ethicon, any other mesh products?
MR. RUMANEK: Object to the form.
Q To treat -- let me rephrase it.
Have you used any other polypropylene mesh products besides those made by Bard and Ethicon to treat prolapse or incontinence in the pelvic area of women?
MR. RUMANEK: And he's already mentioned Coloplast.
MR. BENTLEY: Okay. Thank you. Coloplast. We'll go through it.

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A I believe I may have used one of the AMS devices and I think I've used a Boston Scientific device as well.
Q So going to the beginning, you initially used an Ethicon TBT classic for incontinence around '98; is that correct?
A Correct.
Q And then after that, do you have any recollection of what mesh product you used next for incontinence or prolapse?
A I think I was using the Uro-Tex, which is from Bard, for a period of time.
Q And what is Uro-Tex used to treat?
A Stress urinary incontinence.
Q Do you recall when you switched or started using that in addition to the Ethicon product?
A I believe I started using that when I joined the university in 2000.
Q And when you started using the Uro-Tex, was there a reason you switched to that product instead of TBT or did you continue to use both of them?
A You know, I can't remember. I think maybe they didn't have it here when I arrived and so I used the Bard.

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Q And then around 2000 you began using the Bard Uro-Tex to treat stress urinary incontinence. What's the next polypropylene-based product that you used?
A For stress urinary incontinence?
Q Sure.
A I think I went back to the TBT after that.
Q And then around when did you start using polypropylene to treat prolapse?
A Probably early 2000s, prior to 2000- -- prior to PROLIFT, I was using free-cut graft.
Q And is it your testimony that you were using either a Bard mesh or Ethicon Gynemesh mesh?
A Correct.
Q Did you have any preference to either of those meshes or it was just what was available at the hospital?
A Basically what was available.
Q And then did you continue using whatever was available at the hospital until the kits came or was there any -- did you change your preferences before the kits were available for treating prolapse?
A You know, I don't recall exactly what went into the thought process of what I was using at the

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time.
Q Sure. Did you have similar efficacy results in your opinion regardless of whether it was the Bard mesh or the other kind of mesh to treat prolapse?
A I believe so.
Q And likewise, did you have similar complication rates regardless of whether it was a Bard mesh or the Ethicon mesh in treating prolapse?
A You know, I don't recall specifically.
Q You don't recall any differences between the two?
A Correct.
Q And so that was around 2002, 2003 possibly, and then PROLIFT came to market around 2005; is that correct?
A Correct.
Q Was PROLIFT the first polypropylene-based mesh kit that you used to treat prolapse?
A Correct.
Q And how did you become to use PROLIFT?
A Basically I was introduced to the product through probably a sales rep, and I think I started reading some things about the product, about new products on the market, progressed from there.

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Q And did you attend a training session for PROLIFT?
A Correct.
Q And do you remember who you trained under?
A I believe it was Jaime Sepulveda.
Q And where was that training, if you recall?
A I remember being in Miami, that may have been a preceptor, but I don't remember exactly where the training per se I did, the cadaver training was.
Q And do you recall if that was in 2005?
A Probably right around that period of time, yeah.
Q And before -- let's back up a little bit. Before you started using the free-cut mesh products made from Bard and Ethicon to treat prolapse, how were you treating women with prolapse?
A With biologic grafts and plication, native tissue repair.
Q What biological grafts were you using?
A I don't remember exactly what the brand names were at the time. They were --
Q Were they porcine or do you remember?
A There was -- I think there was a Cavender fascia graft and also Bard made -- I don't remember

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what -- Pubcall or Pubalace [phonetic]. It was either a porcine, but I don't remember exactly what it was.
Q And then you said you were also doing native tissue repair at that time?
A Correct.
Q And how were you -- how would you decide which treatment to recommend for any given patient with prolapse? You know, when you had biological grafts and native tissue repair options, what was your process for deciding which one you thought was best for the patient?
A It completely depended upon the circumstances.
Q So what circumstances would have made the biological graft the appropriate -- in your opinion, the appropriate treatment recommendation?
A Patients with prior failures, potentially a patient with just subjectively poor tissue quality. Those are the two most prominent ones that come to mind.
Q And that's for the biological grafts, right?
A Right.
Q And so I think based on that answer, you

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would have recommended native tissue repair for patients that had not had prior failures; is that correct?
MR. RUMANEK: Object to the form. Mischaracterizes the testimony.
A Repeat that one more time.
Q Well, who would you -- I think you just described the biological grafts you used for patients maybe with prior failures who had subjective tissue weaknesses or problems; is that correct?
A Correct.
Q And so patients that didn't have prior failures and that didn't have this objective tissue quality issues, would those have been in the patients you would have recommended native tissue repair?
A Not necessarily.
Q Well, who would you have recommended native tissue repair to?
A It all depends on the circumstance.
Q Right, and I'm trying to figure out those circumstances here.
A Well, again, there's a lot of factors that come into play --

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Q Right.
A -- so I couldn't give you a specific broad answer for that, but maybe a native tissue repair might have to do with age, patient counseling, things like that.
Q So using your first condition, age, how would that play into your decision of whether or not to recommend native tissue repair?
A Well, it depends, because your first attempt to fix prolapse is usually your best shot at it, and so based on age, type of work they do, the failure rates associated with native tissue repair, generalized counseling. So there isn't -- you know, I'd need a specific event, you know, a specific patient and their profile to give you that, you know, more specific answer.
Q So I still just don't understand. You said that based on age, you may recommend native tissue repair for a given patient.
A Right.
Q So if they were younger, would that lead you more likely to recommend native tissue repair as opposed to a biological graft; is that --
A Not necessarily, because the younger you are, the more chance you have for failure, and

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failure has been established for native tissue repair to a certain degree. So again, it really depends on the circumstances.
Q So older patients would be the ones you would be more likely to recommend native tissue to -- repair to?
A In some cases.
Q So for a younger patient, what would you recommend back in the day before you were using polypropylene mesh products?
MR. RUMANEK: Object to the form.
A I would -- for a younger patient prior to polypropylene, I was mainly doing native tissue repair, however, intra-operatively if I talked to them ahead of time about using biologics and I thought that subjectively the tissue quality was lesser than what I would have wanted, then I may have put a biologic in.
Q And then if the tissue quality was not subjectively problematic or had quality issues, if the tissue looked okay and they were a little bit younger, that would be more likely your recommended patient for native tissue repair; is that correct?
A Not always, but typically correct.
Q Generally, right. And I appreciate that

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there's exceptions and everything's very individualized, but we're trying to understand, you know, how you thought what was appropriate for any given groups of patients, okay?
A Okay.
Q And I think you mentioned that, you know, there was some failure issues with native issue repair, which might have made you recommend other options sometimes; is that correct?
A Correct.
Q And you're referring to your personal experience, you had a lot of failures with native tissue repair?
A Not necessarily.
Q Right, and you're talking about maybe some literature that indicated there was failure rates; is that --
MR. RUMANEK: Object to the form.
A Well, a combination. Also another problem with native tissue repair is that you do some excision of the vaginal wall and that can create dyspareunia and so forth. It's also something to take into consideration.
Q Yeah, and that wasn't really my question. In your personal experience, did you have high

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failure rates with native tissue repair?
A I couldn't tell you specifically.
Q I mean, if you were having --
A Well --
Q -- problems with native tissue repair, would you have been doing it -- would you have been performing that procedure on your patients?
MR. RUMANEK: Hold up. Object to the form.
A What do you define as failure?
Q Well, I'm asking you, Doctor. You're -- you testified that there was issues with failure of native tissue, and I'm trying to see if you're making a statement based upon your personal experience doing this procedure, if you had patients that were having massive failure rates or if you're just basing that on the literature? Do you understand kind of the distinction I'm making?
A Yes, a combination of the two. I mean, there weren't massive failure rates --
Q Right.
A -- but the literature also points to a higher failure rate with native tissue repair, and so taking these all into consideration.
Q And we'll talk about the literature. I'm

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kind of right now trying to flush out what your personal experience came to be --
A Right.
Q -- because you would agree every patient's different, right?
A Uh-huh.
Q And every doctor's different surely, right?
A Right.
Q And different surgeons have different opportunities to do more surgery versus others, right?
A Correct.
Q And you would agree that higher -- doctors that do more frequent surgery have -- probably have higher success rates, right?
MR. RUMANEK: Object to the form.
A Correct.
Q The literature shows that, right?
A Correct.
Q And you're a fairly busy surgeon doing these surgeries, right?
A Correct.
Q So we would expect your surgery failure rates to be pretty good, right?

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MR. RUMANEK: Object to the form.
A Failure rates to be pretty low, you mean?
Q I'm sorry, your success rates are going to be pretty high, right?
MR. RUMANEK: Object to the form.
A I'd hope.
Q Right, because you're -- I mean, part of the reason -- I've seen documents, you're a great surgeon, but you're also a busy surgeon, so you have lots of experience, right?
A Correct.
Q All right. So you were doing biological grafts and native tissue repair prior to 2002 generally before the mesh -- the free mesh box came on, and then around 2005 you started using a PROLIFT kit; is that correct?
A Correct.
Q And when the PROLIFT kit -- when you became -- when you were trained on PROLIFT and you started using that, did you still continue to use biological grafts in your practice?
A I don't recall specifically, but I think I was transitioning over at that point.
Q You would have still done native tissue repair based on some patients, though, at that time,

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right?
A Possibly.
Q Right. So is it fair to say maybe polypropylene kits like PROLIFT would have replaced largely your biological grafts that you were using as one of the surgical options for prolapse once they came on the market?
A Correct.
Q And then after 2005 when you started to use PROLIFT, did you continue to use that product or when did you -- let me rephrase it.
After PROLIFT came to market and you were trained on it and started to use that, did you continue to use that for several years?
A Correct.
Q And did you incorporate or were you trained on another mesh product after the PROLIFT to treat prolapse?
A Yes.
Q And what was the next product that you had?
A I believe it was Avaulta.
Q And who makes Avaulta?
A Bard.
Q And when were you trained on Bard Avaulta,

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if you remember?
A I don't remember exactly when it came out, no.
Q But it's your recollection that you probably trained on it somewhere around the time when it came out?
A Correct.
Q It seems like you're a -- fairly early a doctor, or you want to look at the new products that came out; is that correct?
A Correct.
Q Did you incorporate the Bard Avaulta into your practice after you trained on it?
A I believe I did, correct.
Q And so once you began incorporating the Bard Avaulta into your practice, were you still simultaneously also using the Ethicon PROLIFT?
A I believe I was, correct.
Q And was there some thought process that you would use to decide whether you wanted to use an Avaulta versus a PROLIFT for any given patient?
A You know, I was still trying to get a feel for what I thought was the most -- you know, the best procedure for the patients, so it was sort of a feeling-out process.

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Q And I think I've seen some documents. You didn't necessarily follow the IFU procedural steps on the PROLIFT step by step, I think you had some tricks that you might have employed; is that correct?
A Correct.
MR. RUMANEK: Object to the form.
Q And when you were designing the Coloplast Exair, would you have kind of incorporated your personal experience in customizing the procedure to get what you thought was the best product for treatment of prolapse?
MR. RUMANEK: Object to the form.
A Correct.
Q So after you trained on PROLIFT and began using that in 2005 and then when Bard's Avaulta came to market and you trained on that, what was the next mesh-based kit that you would have learned or began using?
A So go back and restate it, the --
Q I'm just trying to figure out, the first kit you used for prolapse, I believe, is PROLIFT, right?
A Correct.
Q And then the next one, I think, was Bard's

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Avaulta?
A Correct.
Q And then after that, did you train or use any other kits to treat prolapse?
A I believe I trained on the AMS and the Boston Scientific but never adopted those, and I eventually was back using PROLIFT again.
Q All right. And when you trained on the AMS and Boston Sci PROLIFT kits, was there any reason you didn't incorporate those into your practice?
MR. RUMANEK: Object to the form.
A You know, I don't remember the specifics to it, but for whatever reason I had at the time, I just didn't feel as though they were as good of a product as the PROLIFT.
Q Was that based upon your evaluation of like the trocars or the mesh or what -- I'm just trying to figure out what --
A Probably subjective quality of mesh, the technique, the shape of the mesh, you know, all these factors come into play.
Q Right. And to be clear, the kit is not just a piece of mesh, it's a procedure actually that comes with instruments that are used specifically

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for that mesh to implant that device, right?
A Right, it's a kit with -- with instruments for implanting it and the mesh graft itself, correct.
Q And the instruments that -- for implanting it, I'm assuming they're called trocars or cannulas, those are different for each kit, right?
A Same concept but a little different design.
Q And the design kind of dictates a little bit of a different procedure for each kit; is that correct?
A Not necessarily. I mean, as the physician, you can use them any way you want.
Q Right. But at least the IFU procedural steps are going to be tailored to that specific instrumentation that comes with the kit, right?
A Correct.
Q When did you start working on designing the Coloplast Exair?
A I couldn't tell you the actual exact date.
Q Around what year?
A It was probably about two years or so before it came out, so I -- I don't remember exactly what year it came out. Maybe 2010 or so, so maybe

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2008.
Q What was different about that product as compared to the kits that were already marketed?
A What was different about it? Well, it was specifically focused on the technique that myself and a colleague developed.
Q Was that kind of the technique that you used or that was kind of your customized PROLIFT technique that you developed; is that correct?
A Correct.
Q And briefly what customization to the PROLIFT technique did you incorporate, if you can simplify that?
A So the PROLIFT uses a transobturator pass for an anterior repair for the apical portion of the suspension, and the Exair uses a transgluteal pass for the apical portion of the suspension.
Q And I would assume if you're changing it, there's some benefit that you saw, or why would you have changed the transobturator to a transgluteal pass?
MR. RUMANEK: Object to the form.
A My perception was that it gives better apical support.
Q So we're talking it would be a better --

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hopefully a better efficacy rate doing that change as compared to the original PROLIFT procedure?
MR. RUMANEK: Object to the form.
A In terms of failure, correct.
Q Right. Did that -- in your experience did changing the transobturator approach to the transgluteal approach actually have better success rates?
A In my opinion, correct.
Q And you testified that it was a couple of years before the Exair came out is when you first started working on it; is that correct?
A Correct.
Q Do you recall when that would have been?
A When I started working on --
Q Sure. I don't know when Exair came out, so I'm trying to go back two years.
A Yeah, I don't remember exactly when it came out either. So do I recall when I started using this new technique?
Q Sure, let's start there. That's a good idea.
A I don't. I don't. Sometime between when PROLIFT came out and Exair came out. You know, I couldn't tell you exactly.

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Q Were you using that technique when you were doing free-cut Gyenmesh before PROLIFT was out?
A No, because there weren't any trocars available.
Q Doctor, do you know what a key opinion leader is?
A I have ideas.
Q What's your idea?
A My idea is that it's someone who, you know, is respected within the medical community who has an opinion on a certain topic.
Q Do you consider yourself to be a key opinion leader?
A Yeah, in a --
Q Do you know --
A -- circumstance.
Q -- if manufacturers of medical devices for prolapse consider you a key opinion leader?
MR. RUMANEK: Object to the form.
A I don't know.
Q Have you ever worked as a KOL, or key opinion leader, for Ethicon?
MR. RUMANEK: Object to the form.
A I don't think I was.
Q Have you ever worked as a KOL for any

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manufacturer?
MR. RUMANEK: Object to the form.
A Probably with Coloplast, I assume.
Q Okay. I'm going to hand you what's being marked as Exhibit 3, and that's a copy of your report; is that correct?
(Exhibit 3 was marked for identification.)
A Yeah.
Q And --
MR. RUMANEK: Let me just look at it.
MR. BENTLEY: Let me give you a copy.
Q On the last page it indicates that you signed the report on February 15th, 2017; is that correct?
A Correct.
Q And is that consistent with your recollection of when you finished this report?
A Correct.
Q And do you stand by all your opinions in this report?
A Yes.
Q Is there anything that you need to add or change in this report as you sit here?
A Not as I am aware.
Q And does this report provide a complete

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and accurate list of the opinions you intend to offer at trial?
MR. RUMANEK: Object to the form.
A Correct.
Q And does this report contain the bases for your opinions --
MR. RUMANEK: Object to the form.
Q -- contained within?
A In general, correct.
Q And in this report, there's some citations. How did you come to decide which -- which literature to cite in this report versus which ones made it on your reliances?
A Just in reviewing the body of literature, as I constructed the report, I found different articles that -- that supported my thoughts.
Q All right. I'm going to hand you what's being marked as Exhibit 4, which is, I believe, a copy of your reliance list. And this is the supplemental one that was produced recently.
(Exhibit 4 was marked for identification.)
BY MR. BENTLEY:
Q So generally there's a lot of articles listed on your reliance list; is that correct?
A Correct.

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Q But there's not nearly as many cited in your report, right?
A Correct.
Q So I'm just trying to synthesize down how you -- how some of them made it in your report versus not all of them. I totally understand you can't cite or discuss every article in here because that would just be impossible, because I would still find something that you didn't, trust me.
MR. RUMANEK: You just answered your own question.
A I stand by your answer.
Q Do you feel that the articles that you discussed in your report are more important to your opinions generally, or what's the significance of the citations that are in your report to specific articles?
A Repeat that one more time.
Q What's the significance of the articles that you've chosen to cite in your report? What's the significance on those articles as opposed to the -- you know, the large list of articles that didn't make it into your report, you know, direct citations in your report?
MR. RUMANEK: Object to the form.

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Q Do you understand my question?
A Yeah.
MR. RUMANEK: I'm going to object just to the broad scope of the question. Go ahead.
A Well, they support my opinion.
Q What about articles that don't necessarily support your opinion? You reviewed articles that are contrary to your opinions, right?
A Correct.
Q And you would agree that there's substantial literature out there that isn't necessarily in line with your opinions, correct?
MR. RUMANEK: Object to the form.
A Correct.
Q And there is -- there's mixed literature out there on this subject, correct?
A Correct.
Q And you chose articles that supported your opinion to directly discuss in your report; is that correct?
A Correct.
MR. RUMANEK: Object to the form. If you'll -- y'all are kind of talking quickly. If you'll give me a chance after he asks a question. And, Greg, make sure you let him

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finish his answer before you start your question.
Q So in addition to the literature that's -- what did I mark it as, 4?
In addition to the literature that's discussed in Exhibit 4, your reliance list, and in addition to the literature discussed in your report, one of the other bases for your opinions is, of course, your clinical practice and your experience, right?
A Correct.
Q And in your clinical practice, you maintain a database of the patients you've treated for prolapse; is that correct?
A Correct.
Q And I think I've seen different figures, but you have approximately 450 to 500 patients in that database; is that correct?
A Correct.
Q And I think also I've seen that you've treated or done at least a thousand surgeries for prolapses; is that correct?
A Correct.
Q So what happened to the other 500 patients that aren't in your database, are those not mesh

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implants?
A Correct.
Q So your database only tracks mesh implants; is that correct?
A Vaginal mesh implants, correct.
Q Oh, okay. Why did you not want to -- or let me back up.
Do you do abdominal repairs of prolapse using mesh products?
A Correct.
Q Why didn't you want to track those in your database?
A It's an entirely different procedure.
Q All right. So the purpose of your database was specifically to tract transvaginally placed mesh-based products; is that correct?
A Correct.
Q So you're not tracking any biological grafts in your database either?
A Correct.
Q So I guess enrollment in your database has kind of slowed down?
A Correct. You're killing my database.
Q In your database, which is only including transvaginally placed polypropylene products to

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treat prolapse, does that database include -- let me back up.
What products do you track in your database?
A Transvaginal mesh, correct?
Q Right. And when --
A Products specifically?
Q Right.
A We were --
Q Or do you -- in your database, do you keep a data point as to what product specifically it was?
A Correct.
Q All right. And what products are in your database?
A PROLIFT --
Q Yeah.
A -- PROLIFT+M, and the Exair.
Q And what about the Bard Avaulta?
A I don't believe so.
Q But you were -- I think you testified that you trained on Bard Avaulta and you were using Bard Avaulta once it came out, right?
A Yeah, I'm trying to remember whether there are some Avaultas in there. You know, that's a good question.

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Q Would it be pretty easy for you to figure out what numbers for which products are in your database?
A Yeah, I could get that, correct.
Q Have you looked -- in preparing your report, did you go back and look at your database to see what numbers -- did you go back and look and see how many PROLIFTs are in your database?
A No, I just looked at the total number of patients.
Q Doctor, do you treat patients who have complications after having a polypropylene mesh implant for -- implanted for prolapse?
A Yes.
Q And approximately how -- or approximately how often do you treat women who have complications from meshed-based prolapse repair?
MR. RUMANEK: Object to the form.
A Treat surgically --
Q Yeah.
A -- or consultation-wise?
Q Surgically.
A Surgically. How often as in a number?
Q Yeah.
A I'd say in a given year, probably, I don't

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know, maybe 20, 30.
Q And roughly do you do about ten prolapse procedures a month; is that --
MR. RUMANEK: Object to the form.
A No.
Q How many -- on average per month how many women are you doing surgical repair for prolapse?
A Depends on the month. I would say, let me think about it, probably around 15 or so, maybe 15, 20.
Q And has that been generally consistent throughout your practice or --
A Yeah, it's increased over a period of practice. Fluctuates on a monthly basis.
Q Sure. But on average you've done around 150 procedures for the treatment of prolapse during your career; is that fair?
MR. RUMANEK: Per year?
Q Per year.
A Per year? Maybe -- let's see. What did I say? Maybe 15 or 20 a month --
Q Right.
A -- so ten months would be --
Q 140, 150, just generally, right?
A Yeah.

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Q And so maybe 140, 150 women per year you're treating for prolapse. And you just testified that you do about 20 to 30 surgical revisions for women that have suffered complications from a mesh-based PROLIFT repair?
MR. RUMANEK: Object to the form.
A No, not necessarily.
Q Well, how many -- I'm trying to figure out how many -- how often you treat women who have had complications for -- complications that arise after a mesh-based repair for prolapse.
MR. RUMANEK: Let me just -- are you saying after a mesh-based product --
MR. BENTLEY: Well, you wouldn't have a mesh complication before a procedure --
MR. RUMANEK: -- procedure? Are you saying -- no, no, but you're --
MR. BENTLEY: -- because that's --
MR. RUMANEK: I just want to make sure the question's clear because at one point --
BY MR. BENTLEY:
Q Do you understand my question, Doctor, or do you want me to rephrase it?
A So when you said mesh-based --
Q All right. So after a woman has been

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treated with a mesh product for prolapse --
A Right.
Q -- sometimes they develop complications, you would agree with that, right?
A Correct.
Q And a lot of times -- let me rephrase that.
Sometimes those women that have a complication after a mesh-based product implanted for prolapse, sometimes those complications necessitate a surgical repair, correct?
A Sometimes.
Q Which can require -- which can sometimes be cutting out, or excising, some of the mesh, right?
A Correct.
Q And I'm trying to see how often or how many women you've treated in that situation, okay?
A Okay.
Q Because some surgeons don't really treat complications, they refer them out, right?
A Right.
Q And is it your general practice to treat complications that come to you or do you refer them out?

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A I treat them.
Q And so I'm just trying to get numbers on how often that is as -- to get a big picture compared to how often you're doing other things, okay?
A Okay. All right.
Q Some surgeons, that's like their speciality, that's all they do all day, right?
A No. Thank God.
Q I mean, it's a fairly specialized practice, right?
MR. RUMANEK: Object to the form.
Q You would agree that some people that are implanting mesh products really just don't have the expertise to take them out?
MR. RUMANEK: I'm going to just make sure he lets me object to form before you answer.
Q Do you understand my question?
A Repeat it one more time.
Q You would agree that some doctors that are putting in mesh products or that were putting in mesh products didn't necessarily have the expertise to take them out?
MR. RUMANEK: Object to the form.
A Didn't necessarily have the expertise to

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take them out?
Q Right.
A Yes. In general, correct.
Q It's a little bit more of a specialized practice, right?
MR. RUMANEK: Object to the form.
A Yeah, I think some people tend to do it more often than others, correct.
Q It's more invasive to go take it out than to put it in a lot of times, right?
A Not necessarily.
MR. RUMANEK: Object to the form. And again, just -- y'all are talking quickly, and you're probably making the court reporter pull her hair out. Just make sure -- give -- breathe for a second after he asks the question so I can have a chance to object.
Q So in the last -- let's talk about the last year, and we can see if the numbers have changed throughout the years. Generally in the last year, how many women do you think on average you've had to surgically repair a mesh-based product in a woman?
MR. RUMANEK: Object to the form.
A In this past year --

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Q Sure.
A -- 2017?
Q Like right now, how often are you seeing women that have complications that you have to do a surgical repair?
A You're talking about specifically for incontinence, vaginal, or sacrocolpopexies?
Q You can give me -- we can start broad. How often are you treating women that have mesh implant that are having problems that need surgery?
MR. RUMANEK: Object to the form.
A This year, 2017, I've probably had about three so far.
Q So one a month generally?
A Yeah.
Q And last year approximately how many women do you think you treated surgically for a complication that arose from a mesh-based repair?
MR. RUMANEK: Object to the form.
A My guess would be maybe around ten or so.
Q Maybe -- probably once a month is still consistent; is that correct?
A Yeah. It comes and goes in streaks, yeah.
Q And has that been consistent throughout the years in your practice or has it increased or

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decreased?
MR. RUMANEK: Object to the form.
A It fluctuates. There's no real consistency or inconsistency.
Q So have you had substantially more than one a month?
MR. RUMANEK: Object to the form.
A Sometimes I have --
MR. RUMANEK: Object to the form.
A At some times I've had more than one. Sometimes I've had none.
Q So generally -- or let's back up.
Do you track how many revision surgeries you do?
A No.
Q Why not?
MR. RUMANEK: Object to the form.
A It's just part of the practice. Just I haven't made it a point to follow it.
Q You don't think it's important to track how many women are undergoing surgical procedures after they've had a complication from a mesh-based repair?
MR. RUMANEK: Object to the form.
A Well, I see --

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MR. RUMANEK: Mischaracterizes his testimony.
A I see them for a follow-up visit, but I'm not physically tracking them in a database.
Q Do you think that information is important?
MR. RUMANEK: Object to the form.
A To whom?
Q I'm asking you, to you. To you as a practicing physician that's treating women every day, you don't think it's important to track how many women are undergoing surgical procedures to repair a mesh -- to repair mesh-based complications?
MR. RUMANEK: Object to the form. Mischaracterizes his testimony.
A Yeah, I think it's important to be knowledgeable about who you're treating, but I don't make it a physical point to -- I'm not looking to publish a study on it.
Q Do you think it's important for the women you treat to tell them how often you're seeing women that have problems that necessitate a second procedure to treat complications?
MR. RUMANEK: Object to the form.
MR. BENTLEY: You can have your objection

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to the form, that's fine. Let's just keep it to form because we have three hours.
Q That's important for patients, right, Doctor?
MR. RUMANEK: Object to the form.
A Repeat the question.
Q Is it important for the women you treat and you talk to and you counsel about surgical operations, is it important for them to know how often you're seeing women who have complications that require surgical intervention?
MR. RUMANEK: Object to the form.
A Well, it's part of my consent.
Q It's important for the patients, right?
MR. RUMANEK: Object to the form. Asked and answered. You've asked -- you're --
MR. BENTLEY: Counsel. Counsel.
MR. RUMANEK: You're asking --
MR. BENTLEY: You got form, that's it.
MR. RUMANEK: Okay.
MR. BENTLEY: You're wasting my time.
MR. RUMANEK: You're asking questions --
MR. BENTLEY: The record is what it is.
MR. RUMANEK: You're asking questions over and over.

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MR. BENTLEY: I entirely disagree. The record speaks for itself. If we keep doing this, I'm going to ask for more time. I'm already put in a -- I'm keeping the deposition open because we didn't get any of the documents I requested. I'm requesting all the case log summaries and stuff, which is directly reliable -- or relevant to his opinions. We're keeping the deposition open for that.
MR. RUMANEK: I don't --
MR. BENTLEY: If we keep wasting time with speaking objections, I'm going to go back and ask for more time.
MR. RUMANEK: Object to the form. Asked and answered.
MR. BENTLEY: Respectfully form. Thanks.
BY MR. BENTLEY:
Q Doctor, you track transvaginal mesh implants in your database, right?
A Correct.
Q Because you feel it's important information to keep track of, right?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. And that's important for women

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that are choosing which procedure to undergo to correct or to treat their prolapse, right?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. And it's also important for women to know how often you're seeing other women that have been -- that have undergone mesh-based repair and have had to have surgical intervention because of complications? That's important information for women, right?
MR. RUMANEK: Object to the form. Asked and answered.
A I base my counseling on my experience.
Q Right. And your experience includes treating women, doing additional surgery on women who have had products implanted, right?
MR. RUMANEK: Object to the form.
A My specific counseling has to do with my database and my numbers because there's tremendous variability in the physicians who implant it and the circumstances.
Q What creates the tremendous variability in different physicians, it's -- expertise, is that one?
MR. RUMANEK: Object to the form.

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Q Is that one aspect that would create variability from different physicians?
A It's one component, correct.
Q So expertise. Would it be training, who they trained under and where they were, is that one component?
MR. RUMANEK: Object to the form.
A Potentially.
Q Would it be the frequency with which they perform the procedures?
MR. RUMANEK: Object to the form.
A Potentially.
Q Would it be their knowledge, you know, and their -- how tied in they are to the literature and the industry of these devices, do you agree there's variability in that?
MR. RUMANEK: Object to the form.
A No.
Q You think that every doctor reads exactly every article that you read?
MR. RUMANEK: Object to the form.
A No.
Q Different doctors read different journals, right?
A Correct.

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MR. RUMANEK: Object to the form.
Q Different doctors read different journals?
A Correct.
Q Right. And different journals are for -- are catered to different specialities, correct?
A Correct.
Q Some journals are catered to obstetrics, correct?
A Correct.
Q Some are catered to gynecology, correct?
A Correct.
Q Some are catered to urology, correct?
A Correct.
Q Some are catered to pelvic reconstructive surgery, correct?
A Correct.
Q And not every doctor necessarily reads every one of those journals, right?
A Correct.
Q There's a differing level of edu- -- or a differing level of knowledge depending on any one doctor's specialty, right?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. Doctor, when you've treated

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patients who have had a complication after a mesh-based repair, what complications have you seen?
A Mesh-based repair, are we talking sacrocolpopexy, transvaginal --
Q Well, I'm sorry.
A -- prolapse?
Q Is it your opinion that there's different mesh complications based on the approach?
A Correct.
Q And so what complications have you seen after a transvaginal mesh-based repair for prolapse?
A Erosions, or exposure in the vaginal canal. I have seen failures. I've seen overcorrections. I've seen irritative voiding symptoms. I've seen overactive bladder symptoms in general.
Q I think I heard you say overcorrections?
MR. RUMANEK: Were you -- I just want to make sure you were finished.
Q I'm sorry, are you done?
A Yeah.
Q I didn't mean to cut you off. Generally is it -- all right. Overcorrection, is that -- are you talking about too much tension on the mesh, is that --

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A Not necessarily. I mean, some patients -- well, let me rephrase that.
Not necessarily an overcorrection. Some patients can develop urinary incontinence after any prolapse procedure.
Q They consider -- I'm sorry.
A So sometimes when they develop urinary incontinence, it's -- it was an underlying problem that now manifests itself.
Q And you're calling that an overcorrection?
A No, I take that back.
Q Right.
A It's not an overcorrection.
Q But if -- these are supposed to be implanted with tension free, right?
A Correct.
Q And if there's too much tension on the mesh implant, that could be problematic for the patient; is that fair?
A Not necessarily.
Q Can it be?
A It can.
Q What can happen if there's too much tension placed on the mesh after it's implanted?
MR. RUMANEK: Object to the form.

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A For an incontinence procedure retention?
Q Right, for a prolapse procedure.
A It varies.
Q And let's talk about the varying gamut of what can happen if there's too much tension on a mesh product after prolapse.
A Well, you can tear the graft. You can -- potentially too much tension, you could -- it's theoretical as to whether that causes pain or not. It's really --
Q You don't have an opinion one way or another?
A Correct.
Q You haven't seen any literature that too much tension causes pain?
MR. RUMANEK: Object to the form.
A Yeah, I came across that --
Q You just discount it?
MR. RUMANEK: Object to the form.
A No, I just don't necessarily agree with it.
Q What reasons do you not agree with that?
A Because nobody really knows the etiology of pain because patients who have graft repair and non-graft repairs, in general pain is a risk.

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Q No other reason for discounting that literature as you sit here today?
MR. RUMANEK: Object to the form.
A No other reason for discounting it. It's not that --
Q Well, let me back up. You agree that -- I'm sorry, not to cut you off, but that was a bad question.
You agree there's some literature that suggests or indicates that too much tension can cause pain; is that fair?
A It's been stated, correct.
Q Right. And you disagree with that literature, correct?
MR. RUMANEK: Object to the form.
Q And -- correct, you disagree --
A I wouldn't say I necessarily disagree with it. I just have not -- you know, I respect that that's a finding in some of the literature, but I also state that pain is a very common side effect of pelvic surgery, and so I think it's impossible with medical certainty to say that that pain necessarily has to do with tension of the graft.
Q Have you studied -- I'm sorry, are you done?

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A Yeah.
Q Have you studied that specific question?
A Just in my own -- no, not specifically, I've not studied it.
Q But is -- but there's some people that have tried to study it, and it's a difficult question, right?
A Correct.
Q And you would -- I'm just trying to figure out what reasons -- what other reasons you disagree with those findings from studies that have tried to look at it, and I think I heard you say that, well, there's pain, you know, that can happen with anything. I understand that. That's one of your explanations, right?
MR. RUMANEK: Object to the form. Compound question.
A Yeah, pain would happen --
Q And do you have any other reasons or explanations for disagreeing with those studies as you sit here today?
MR. RUMANEK: Object to the form.
A No.
Q When you're treating women who have suffered complications after having a mesh product

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implanted for prolapse, have you ever seen mesh that's bunched?
A I've seen -- repeat it one more time.
Q In treating women who have complications -- women come to you for complications sometimes after they've had a mesh implant for prolapse, right?
A Correct.
Q And you're familiar with the term "mesh bunching"?
A Correct.
Q And have you ever seen in your personal practice women suffering from mesh bunching, who have their mesh that has -- presents as being bunched?
A I have seen patients who have mesh that's bunched up with absolutely no symptoms at all and I've seen patients who have mesh that's bunched up with possibly a symptom associated with it. So it's impossible to conclude that mesh bunching is the -- part of their pain.
Q And that wasn't really my question. I was just asking, you've seen mesh bunching when you're treating women with complications, right?
A Correct.

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Q Right. And have you seen women -- in treating women that have complications, have you seen where the mesh is roped?
A Not necessarily as their complication, but correct.
Q Right, I'm not trying to make any causation leap here --
A Okay.
Q -- I'm just -- in your experience, you understand what mesh roping is, right?
A Correct.
Q And I'm just asking, have you seen it when you're treating women -- well, because presumably you wouldn't see mesh roping -- let me strike that.
Have you ever seen mesh roping in a woman that doesn't present to you with complications?
A Yes.
Q All right. And how do you see the -- have you ever seen a woman present to you who's had a mesh implant for prolapse and you've noticed that the mesh had roped?
A Correct.
Q And you -- when you've seen women with roped mesh, sometimes they have complications and sometimes they don't; is that --

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A Correct.
Q And how do you tell that the mesh is roped?
A Palpation.
Q You can feel that the mesh is roped through palpating?
A Correct.
Q And have you ever seen mesh that's curled?
MR. RUMANEK: Object to the form.
A Curled as in a surgical exploration I'm visually seeing the mesh curling?
Q I don't know. Have you seen -- is that how you've seen it?
MR. RUMANEK: Object to the form.
A Yes.
Q Have you -- can you see curled mesh through palpating? Or can you feel mesh -- sorry for the semantics.
A You can perceive as such.
Q Do you appreciate that pore sizes are fairly important for a medical implant like mesh, right?
A According to the literature, correct.
Q Do you have some reason to disagree with the literature?

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MR. RUMANEK: Object to the form.
A Not necessarily.
Q Do you have an opinion that pore size is not an important factor of mesh implant?
MR. RUMANEK: Object to the form.
A I think it's one of the factors.
Q It's -- it's important, right?
A Yeah.
MR. RUMANEK: Object to the form.
Q Do you know what happens to the mesh that's -- once it's roped?
MR. RUMANEK: Object to the form.
A No, I don't.
Q Do you know what happens to the mesh pore size once it's curled?
MR. RUMANEK: Object to the form.
A I can make some assumptions.
Q What would your assumptions be?
A My assumption would be that the pore size may become smaller.
Q And do you have any assumptions as to what happens to the mesh pore size if it's bunched?
MR. RUMANEK: Object to the form.
A No.
Q Do you know what happens if the pore size

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collapses or becomes smaller?
MR. RUMANEK: Object to the form.
A No, not specifically.
Q Have you seen any literature discussing that?
MR. RUMANEK: Object to the form.
A Yes.
Q And what does the literature indicate?
MR. RUMANEK: Object to the form.
A The literature indicates that it could contribute to scar formation.
Q Do you have an understanding of the -- let me -- your report discussed it. You have an understanding of the process of how the body integrates into the mesh, right?
A In theory.
Q And the pore size is supposed to allow for the body to more safely integrate into the mesh, right?
A Correct.
Q And if the pore sizes collapse, that can interfere with that ability of the mesh to integrate into the body, right?
MR. RUMANEK: Object to the form.
A It's one of the theories.

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Q Have you ever seen scar plating --
MR. RUMANEK: Object to the form.
Q -- on mesh?
A I can't say specifically that I know what a scar plate is, but --
Q Do you -- would you want -- when you're implanting a mesh product, do you want to see a hardened scar plate around the mesh, is that a desired outcome for you?
MR. RUMANEK: Object to the form.
A Subjectively, no, but clinically speaking, I don't know what the relevance is.
Q Have you seen literature that suggests there is a clinical relevance to a hardening scar plate?
MR. RUMANEK: Object to the form.
A In regards to pain, but pain's multifactorial.
Q And we discussed --
MR. RUMANEK: We've been going about an hour, so whenever you get to a breaking point.
Q We discussed this earlier, you testified, and correctly, there's many etiologies for pain, right?
A Correct.

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Q And one of the theories -- or one of the things the literature suggests is the hardened scar plate can also create pain, you've seen that literature, right?
A I've seen a theory that that could be a contributing factor.
Q And do you have any criticisms or explanations of why you disagree with that theory or literature?
MR. RUMANEK: Object to the form.
A Pain is multifactorial.
Q And I get that --
A Right.
Q -- but specifically literature addressing whether or not a hardened scar plate causes or, you know, leads to increased pain, do you understand what I'm asking, sir?
A Correct.
Q Do you have any criticisms or disagreements or explanation why you discount that theory and that literature?
MR. RUMANEK: Object to the form.
A Well, that scarring occurs with native tissue repairs, any type of surgical repair, and so theoretically everybody's going to have some

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scarring after surgery. And some patients have pain and some don't, so there's no real -- you know, there's no real hard and fast predictability.
Q Right. And you understand there's different levels of scarring, right?
A Subjectively.
Q Sure. And you're not -- you testified you're not looking for a hardened scar plate when you implant a mesh product in a woman's pelvis, right?
MR. RUMANEK: Object to the form.
A Subjectively, I would not look for that, but it doesn't necessarily clinically manifest itself of the problem.
Q And my question is, you're aware that there's some literature discussing the hardened scar plate as opposed to the normal scarification processes, that the hardened scar plate is a contributor to pain syndrome?
MR. RUMANEK: Object to the form.
Q You agree with me that there's literature and analysis and science discussing that, right?
A I agree that pain is quoted as a possible consequence of scarring, but it's not a direct relationship in all circumstances.

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Q And I'm trying to just understand your discount of that literature and that science, okay?
MR. RUMANEK: Object --
Q And I understand that you -- that pain can cause -- can happen with all surgeries and can be caused by lots of different things, I understand that, but specific to the science looking that overly hardened scar plating after mesh implant, that the scientists that have looked at that and decide, hey, this probably creates more pain, in addition to the pain can happen from lots of things, I'm just trying to see if you have any criticisms or explanation of why you discount that science. Do you understand my question, Doctor?
MR. RUMANEK: I'm going to object to the form --
MR. BENTLEY: You can object to form. Thank you.
Q Do you understand --
MR. RUMANEK: -- and your use of the term "discounting."
Q Do you understand my question?
A Yes, but I need to see a specific report to see how they derive their conclusion.
Q And the reason I'm asking is because in

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your report, you don't -- you state that pain can be caused by a lot of things, I understand that, and I don't see any discussion of your criticisms or explanation of that data, and that's why -- today is my only opportunity to find these things out. So I'm just trying to see as you sit here today, do you have any further explanation that you want to add as to why you criticize or discount or you don't buy that hardened scar plate causes or contributes to pain? Do you have anything else to add?

MR. RUMANEK: Object to the form.

A I can look at my report. Which page are we specifically talking about?

Q It's not in there, so I don't have a page really to cite. And so I'm asking you if there's anything else you would like to add today.

MR. RUMANEK: Object to the form.

A To, okay, go back -- in summary, add to the theory about scar plating?

Q No, we've agreed -- I mean, you would agree that there's evidence that a hardened scar plate can cause or contribute to pain, and that's a theory that's been tested, there's some science showing it, right? You get that, right?

MR. RUMANEK: Object to the form.

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A There are some articles that suggest that.

Q Right. And -- and I'm simply asking -- you know, you don't tell me in here why you don't buy that theory. I just -- and I understand that you -- I understand that pain can come from a lot of different reasons.

A Correct.

Q And just specific to that one theory, like is there some problem that you see with that theory or some -- you don't -- the authors aren't reliable, they're poor journals, their analysis is bad? Do you have any scientific bases for discounting that?

MR. RUMANEK: Object to the form.

A Personal experience.

MR. BENTLEY: We can take a break.

(Recess from 9:42 a.m. to 9:47 a.m.)

MR. BENTLEY: And just to clear up the record, on the document request that we were looking at earlier, item 16 on Exhibit A is, "any reports, documents, whether kept in hard copy or electronic form, related to any other matter involving any pelvic mesh product for treatment of stress urinary incontinence or pelvic organ prolapse," and Plaintiffs again request that those document requests are

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responded to and plaintiffs request the reports and summaries regarding that -- Dr. Goldwasser's database regarding mesh-based products for prolapse. And those are relevant to his opinions here and we request those in preparation for trial.

MR. RUMANEK: And let me just note on the record that we've filed an objection to the document requests that were put forward.

BY MR. BENTLEY:

Q Doctor, when did you train on PROLIFT+M?

A I don't remember the exact year, but whenever it was released, which was, I don't know, maybe -- I don't remember exactly when it was released. I want to say a year or two after maybe PROLIFT came out.

Q And we discussed you're a fairly early -- a doctor of new technology; is that fair?

A Right.

Q And you'll look at new technology and decide whether it's appropriate to incorporate in your practice; is that correct?

A Correct.

Q And you looked at, for example, some AMS and Boston Sci products that you didn't incorporate,

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correct?

A Correct.

Q And you did incorporate PROLIFT+M into your practice, though, right?

A Correct.

Q And you wouldn't have done that if you didn't perceive a benefit for the product, right?

MR. RUMANEK: Object to the form.

A It was uncertain as to whether there was a benefit, so --

Q Once you began using PROLIFT+M, you continued to use it, right?

A I believe it was -- I don't recall whether that was the one we used. It may have been the only thing that was available at the time.

Q I'm going to hand you what's being marked as Exhibit 5 and this an e-mail that will hopefully refresh your memory on the time period. You can see it's an e-mail from May 2009. You see that?

(Exhibit 5 was marked for identification.)

A Correct.

Q And the subject's New PROLIFT+M Order; do you see that?

A Correct.

Q And --

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MR. RUMANEK: Just give him a chance to look at it.
Q And PROLIFT+M is just a PROLIFT product with a partially absorbable mesh component, correct?
A Right.
Q And the ultimate goal of that is just to have a lighter mesh implanted in the woman's pelvis after part of the mesh is absorbed generally, right?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. And the potential perceived benefits is that is the mesh will be lighter weight because there's less mesh left at the end, right?
MR. RUMANEK: Object to the form.
A That was the theory, correct.
Q And this e-mail just shows that -- you can see this is from David Jackson writing an e-mail to Ramona Peterson. Do you know either of those people?
A Yes.
Q David Jackson was a sales rep in your territory?
A Correct.
Q And you can see David Jackson says, "I have not told Dr. Goldwasser this info because he

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needs to use the old PROLIFT that you have on the shelf. He did ask me about the new mesh yesterday, and I told him it was still pending"; do you see that?
A Correct.
Q And you can see this e-mail is just them talking about you wanting to try PROLIFT+M, right?
MR. RUMANEK: Object to the form.
A If it says so. I mean, I don't remember, I guess --
MR. RUMANEK: Take -- read that e-mail.
Q It's merely just to refresh the time period. Is this consistent with your memory of when you first trained on and started using PROLIFT+M?
A I don't remember specifically just based on the date on here.
Q Do you have a recollection that's different? Do you think you started using plus M in a different year?
A No, I mean, I honestly don't remember when I did.
Q You don't have any reason to doubt this e-mail, do you?
MR. RUMANEK: Object to the form.
A Doubt what?

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Q You don't have any reason to doubt the accuracy of David Jackson's representation about you wanting to use PROLIFT+M around 2009, do you?
MR. RUMANEK: Object to the form.
A I honestly don't know.
Q But your case log -- does your case log differentiate between plus M and regular PROLIFT?
A Correct.
Q So that's information you could have gotten from your case log, right?
A I believe so, correct.
Q Doctor, have you ever noticed when you're implanting mesh that it doesn't lay flat?
MR. RUMANEK: Object to the form.
A When I'm implanting mesh, it does not lay flat.
Q Well, let me rephrase a little bit.
When you're implanting mesh, are you always conscious to make sure that the mesh lays flat, is that one of your goals?
A It's one of the things that I'm aware of when I'm doing the implantation, correct.
Q But if it doesn't lay flat, that could potentially lead to things we discussed like roping, bunching and other such things, right?

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MR. RUMANEK: Object to the form.
A Not necessarily.
Q What happens if it doesn't lay flat?
A I don't know. It's a problem. Nobody knows.
Q So why don't you just curl it up when you implant it?
MR. RUMANEK: Object to the form.
A Esthetically to me it looks better to lay it flat.
Q Who's looking at it, Doctor?
A I am as I'm putting it in.
Q So the only reason you're making sure the mesh lays flat is for your personal esthetics?
MR. RUMANEK: Object to the form.
A Not at all. My perception.
Q Right. I'm going to hand you what's being marked as Exhibit 6. And this is a Pre-study Questionnaire that was produced by Ethicon to us, and I think this just documents one of the consulting projects you worked on for Ethicon. Do you recall consulting for Ethicon in 2010?
(Exhibit 6 was marked for identification.)
A Not specifically that, but based on what you're telling me.

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Q But you remember -- I mean, it's interesting, the last page has some diagrams of, I guess, your hands and measurements. I think they were looking at designing some new products, do you remember that?
A No, I honestly don't.
Q All right. Well, the first page of this document, it says Pre-study Questions: Dr. Goldwasser; do you see that?
A Correct.
Q And let's try and, I guess, see if this is really you. Do you know what your glove size is?
A Correct.
Q You do know --
A Yes.
Q And is this consistent with your glove size?
A Yes.
Q 7.5, right?
A Yes.
Q And you're right-handed?
A Correct.
Q And this document was made in November of 2010. And the third question states that you've been doing mesh-based repairs for, I guess, prolapse

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for about seven years; is that correct?
MR. RUMANEK: Object to the form.
A If they say so, correct.
Q Well, you would have provided this information to them, right?
MR. RUMANEK: Object to the form.
A It would have been my best guess.
Q Right.
A I mean, I couldn't tell you specifically when I started.
Q And this is consistent with your memory and your testimony today that you started using mesh-based repairs for prolapse around 2003, right?
A Most likely, correct.
Q And question 4 says you do about ten procedures per month, that's consistent with what you've testified to today, right?
A Correct.
Q And what's interesting is question 5, you put -- or they recorded that you're doing 100 percent mesh-based repairs. You would have been using mesh-based repairs for some women and doing native tissue repairs for others; isn't that correct?
MR. RUMANEK: Object to the form.

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A I believe I did some native tissue repairs.
Q Because, like you said, there's no one product that's appropriate for all patients, right?
MR. RUMANEK: Object to the form.
A Not necessarily. I mean, I was using PROLIFT at the time, but I would cut it to different shapes if I needed to, so --
Q Were you still doing native tissue repairs when you were implanting PROLIFT?
A It says 100 percent on here, but my guess is I must have been doing some at the time.
Q And question 6 says you're doing four to five PROLIFTs per month and four to five Exairs per month; do you see that?
A Correct.
Q How would you decide which patients to recommend PROLIFT versus which patients to recommend Exair?
A I wasn't necessarily recommending one or the other to the patients. It probably has to do with at the time, 2010, I was trying to figure out which product may be best long term. There were different components of each product that I thought were favorable.

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Q And what were the components of the Exair that you thought were favorable in comparison to PROLIFT?
A I liked the technique that was specifically, you know, touted in the Exair device.
Q That was your technique.
A Correct.
MR. RUMANEK: Were you done answering the question? I just want to make sure you have a chance --
A I also -- yeah, correct. I also liked the -- I actually like the introducers better on the PROLIFT. I thought they had a better surgical device in terms of cannulas, trocars.
Q But you designed the Exair, why didn't you design the introducers --
MR. RUMANEK: Were you done? I just want to make sure he's done answering the question.
THE WITNESS: Yeah, yeah.
Q You designed -- you helped design the Exair. Why didn't you design the introducers to match what you thought were the best product instruments to implant?
A Because there was a patent --
Q Okay. Fair.

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A -- unfortunately.
Q And really what I just want to draw your attention to is down at the bottom under question 13, you state that one of the reasons you trim the graft was it does not lay flat; do you see that?
MR. RUMANEK: Object to the form, to the characterization.
A Yes.
Q And we were discussing the perceived benefits of mesh laying flat is -- is what?
(Off-the-record discussion.)
BY MR. BENTLEY:
Q Number 13, the question is, "For which specific reasons would you trim the graft?" And your answer is, "Does not lay flat"; do you see that?
MR. RUMANEK: Object to the form. Mischaracterization.
A Yes.
MR. RUMANEK: Did you -- you answer out loud.
A Yes.
Q Yes? No?
And the reason you're trimming it is because it doesn't lay flat. And I'm just -- we're

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trying to figure out what your reason for wanting it to lay flat is, and I think we were discussing this a little earlier, but can you restate why you want the mesh to lay flat in addition to just esthetics?
A Well, my perception is that if it lays flat, it covers more of the surface area where the prolapse is and that theoretically it may be more beneficial for whatever reason. It's really an unknown -- it's an unknown.
Q Well, why would you trim it if you wanted more surface area and wider mesh? Wouldn't having a wider piece of mesh that's not cut cover more surface area?
MR. RUMANEK: Object to the form.
A No. I mean, there's excess mesh on it that you don't need. I mean, you want to use the -- you want to use just what you need. I mean, there's edges that you don't necessarily want sticking out all over the place.
Q Why?
MR. RUMANEK: Object to the form.
A Just my perception.
Q Why in your perception do you not want extra mesh?
A It's not necessarily extra mesh. My

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perception is that you put the device in to do the dissection adequately so that the device can expand and cover the suction area that you're trying to treat.
Q But you're trimming it so there's no extra mesh, right?
MR. RUMANEK: Object to the form.
A I'm trimming it so it fits the patient.
Q So it lays flat in the patient, right?
MR. RUMANEK: Object to the form.
A As flat as I can make it, correct.
Q And why, why are you trying to do that?
MR. RUMANEK: Object to the form. Asked and answered.
A No specific data as to why I'm doing that. It's my perception.
Q So you're operating on patients and treating patients for no perceived benefit or -- what's the perceived benefit?
MR. RUMANEK: Object to the form. Mischaracterizes his testimony.
MR. BENTLEY: I didn't mischaracterize his testimony. I'm asking him a question.
A Well, it's an unknown. Nobody knows how exactly the best method is for any of this stuff.

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Q We're not talking about best method or what everyone else knows. I'm asking you, Dr. -- as Dr. Goldwasser, who trims the mesh so it lays flat, why are you doing that?
MR. RUMANEK: Object to the form. Asked and answered.
A Just in discussions with my colleagues, you know, the perception was is that you want to do the procedure where you lay the mesh flat.
Q Why, though? What's the perceived benefit that you discussed with your colleagues that is associated with mesh laying flat versus crumpled up or not?
A The perceived benefit was possibly less exposure. Nobody knew exactly what to expect from these things. I mean, you're -- you know, this is a process in evolution basically.
Q We're gaining knowledge as the product's out there and we're implanting it, right?
A Correct.
Q As we're treating women, we're continuing to look at it and see what happens, correct?
A Correct.
Q And our --
MR. RUMANEK: Object to --

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Q And our knowledge base is increasing as it's used more, right?
A You'd hope.
Q Right. And you personally are increasing your personal knowledge base using your database, correct?
A Correct.
Q And that's to learn more about the product because it's a new product, right?
MR. RUMANEK: Object to the form.
A Yeah, I mean, it was new and it's --
Q And -- sorry. And new products have different complications associated with them, right?
MR. RUMANEK: Object to the form.
A All products have complications associated with them.
Q Sure. Well -- but you just said you don't know exactly what's going on with this product, we're figuring it out, right?
MR. RUMANEK: Object to the form.
Q Right?
MR. RUMANEK: Mischaracterizes his testimony.
A Correct.
Q And it's a fairly new product, so we're

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just trying to figure out what happens if the mesh lays flat versus not flat, that's one of the things we're looking at, right?
MR. RUMANEK: Object to the form.
A One of the things that I'm looking at?
Q Well, you're looking to keep it flat, right? Let's back up.
This is a new product that we're gaining knowledge about, right?
MR. RUMANEK: Object to the form.
A Correct.
Q And you're attempting to keep the mesh to lay flat because you think there's some perceived benefits, whether or not they're for sure, we don't know, right?
MR. RUMANEK: Object to the form.
A Correct.
Q And you just testified that one of the potential benefits of keeping the mesh flat is reduce complications such as erosion; is that correct?
MR. RUMANEK: Object to the form.
A Potentially, correct.
Q But we don't know necessarily yet because there's not a lot of information available yet?

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MR. RUMANEK: Object to the form.
A There's information available, a lot of information, but they're all theories.
Q Right. But at least based on the information and the theories that you know, you're at least attempting to keep it flat?
A Correct.
Q Doctor, I'm handing you what's being marked as Exhibit 7, and this is, I think, one of your early publications with Dr. Mickey Karram; do you see that?
(Exhibit 7 was marked for identification.)
A Yes.
Q And the title of this is High Uterosacral Vaginal Vault Suspension With Facial Reconstruction For Vaginal Repair Of Enterocele And Vaginal Vault Prolapse; is that correct?
A Correct.
Q And this was --
A 2001.
Q A while ago?
A Correct.
Q And this was published in the American Journal of Obstetrics and Gynecology actually in December 2001; is that correct?

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A Correct.
Q All right. And you're listed as one of the authors on this article, correct?
A Correct.
Q And do you still perform high uterosacral vaginal vault suspensions today?
A Yes.
Q Do you have good results with those?
A Yes.
Q All right. And just briefly, on the third page under Comment on the right --
A Page -- okay. Yes. Yes.
Q It's 1341 at the top.
A Uh-huh. Okay.
Q Under Comment, you state that, "This study and previous reports by Jenkins, Shull, et al, and Barber, et al, indicate that the uterosacral ligaments are durable, usable structures even in patients with advanced pelvic organ prolapse, which supports the concept that these structures do not attenuate but break at specific points. The procedure described in this report not only suspends the vaginal vault but also obliterates the cul-de-sac, thus preventing any enterocele recurrence"; is that correct?

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A Correct.
Q And if you turn one more page to the end, the very last paragraph, you conclude, "A high uterosacral ligament suspension with fascial reconstruction seems to be a durable procedure for vaginal repair of enterocele and vaginal vault prolapse"; do you see that?
A Correct.
Q Is that still true today?
A Yes.
Q And that's one of the options -- the surgical options for treating apical prolapse, correct?
A Correct.
Q Doctor, when you were working with Coloplast to design the Exair, what kind of mesh was used in that product?
A I believe it was called Novasilk.
Q I'm handing you what's being marked as Exhibit 8, and this is something I pulled off the -- I think the Coloplast website, and it's -- looks like an advertisement or a brochure for the Exair Prolapse Repair System; do you see that?
(Exhibit 8 was marked for identification.)
A Yes.

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Q And would you have been familiar with a document like this in using Exair, in helping develop it?
MR. RUMANEK: Object to the form.
A No, I don't think I've seen this before.
Q Well, let's look at it and maybe you can just tell me what you think about these claims. If you'd turn to the second page, it's a description of the Exair, the product that you helped to develop. Does that look like the product you helped develop on the bottom of those pictures?
A Yes.
Q And on the left it says Custom-shaped Novasilk mesh, and that's the mesh that you were describing that's used in this product, correct?
A Correct.
Q And it's a little bit different than the Gynemesh mesh used in PROLIFT, correct?
A Correct.
Q And here the Novasilk is described as light, "Lighter weight and lower density means less implanted material for increased patient comfort"; do you see that?
MR. RUMANEK: Object to the form.
A Somewhere on here.

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Q On the top left under Custom-shaped Novasilk.
A Oh, yeah, yeah.
Q You with me?
A Correct.
Q And it's got a couple of aspects of the Novasilk mesh; do you see that?
A Correct.
Q And the first one is Light and it says, "Lighter weight and lower density means less implanted" mesh -- or "less implanted material for increased patient comfort"; do you see that?
A Yes.
Q And that's kind of consistent with what we were just talking about, that there's a perceived benefit of having less mesh, which is one of the reasons why you would trim the mesh --
MR. RUMANEK: Object to the form.
Q -- is that fair?
MR. RUMANEK: Object to form.
A Yes, over a period of time that became the perception, correct.
Q Right. And next it says Soft -- in that second bullet, it says, "Soft-cut, non-fraying edges help to lessen" mesh -- sorry, let me rephrase it.

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The next under Soft, it says, "Soft-cut non-fraying edges help to lessen risk of extrusion"; do you see that?
A Correct.
Q And I think that's what you testified, that one of the reasons you want to take the extra mesh out is so it's not sticking there potentially extruding or eroding out, correct?
A Yeah. That was one of the perceptions, correct.
Q And it could be a benefit for a patient -- a potential benefit for a patient, right?
A Possibly.
Q And next down it says Porous, "Large pore microfiber knit supports tissue ingrowth and incorporation of mesh into adjacent tissue"; do you see that?
A Correct.
Q And that's kind of -- in part of our discussion, we were talking about the pore size allows for the mesh to incorporate into the body, right?
A Correct.
Q And one of the perceived benefits here is that the large pore of the Novasilk allows it to be

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safely and comfortably incorporated into the body; is that correct?
MR. RUMANEK: Object to the form.
A Correct.
Q And, in fact, Novasilk is described as soft as compared to some other meshes, right?
A Correct.
Q Right. And the last -- or the next one down, Compliant, it says, "Multidirectional elasticity enables anatomic conformance and aids in wrinkle-free positioning"; do you see that?
A Correct.
Q And that's another goal that we've seen -- or we've talked about, is you try to make the mesh lay flat, which is -- here is described as wrinkle free, which is kind of the same thing, right?
MR. RUMANEK: Object to the form.
A Correct.
Q So, you know, this mesh that you -- this mesh product that you helped design has some good benefits potentially for the patient; is that correct?
A Well, correction --
MR. RUMANEK: Object to form.
A -- I didn't have anything to do with the

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mesh design.
Q Well, you designed a product that used this mesh that has these potential benefits, right?
A Correct. But I actually prefer the Gynemesh over this.
Q Right. And I think you prefer the Gynemesh because it was actually stiffer; isn't that correct?
A Correct.
Q And you felt that it had better handling characteristics when you were implanting it as compared to the softer Novasilk, right?
A Correct.
Q But from the patient side, you noted that the stiffness can be more perceived by the patient, though; isn't that correct?
MR. RUMANEK: Object to the form.
A No, I didn't. That was the strange part.
Q I'm going to hand you what is being marked as Exhibit 9. This is another document produced to us by Ethicon, and this is a -- at the top it says Neo usability study 2, Post-study questions; do you see that?
(Exhibit 9 was marked for identification.)
A Yes.

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Q And then the next line, it says, "Dr. Goldwasser asked before he performed the PROLIFT kit." And --
A Who this is from?
Q This is -- you know, at the bottom right, it has the --
MR. RUMANEK: Take a --
Q -- eth.mesh document; do you see that?
MR. RUMANEK: You can review it if you'd like.
A Ethicon, okay.
Q Well, your reliance list indicates you reviewed -- reviewed some internal Ethicon documents, correct?
A Yes.
Q Were you provided this document when you were preparing for this deposition or your report?
MR. RUMANEK: Object to the form.
A It was in my list, correct.
Q Do you recall reviewing this when you --
A I've reviewed hundreds of articles --
Q Did you --
A -- so I couldn't tell you specifically.
Q Yeah, and I'm not talking about articles. I'm talking about the Ethicon documents. You see on

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the bottom right it has the eth-mesh?
A Correct.
Q Right. And you were provided some documents with an eth-mesh on it?
A Correct.
Q And did you -- were you provided any documents that reflected your consulting experience with Ethicon?
A I can't say for sure honestly.
Q You don't remember seeing this document specifically, though?
A Correct.
Q And we were talking about some of the potential benefits of Exair, and I just want to draw your attention down to mesh material, and the question is, "Are you aware of Ultrapro mesh, Gynemesh M mesh, or PROLIFT+M," it continues, and you answered "yes, to all above."
MR. RUMANEK: Object to the form.
MR. BENTLEY: Well, I haven't even asked the question yet, though, I appreciate that.
Q And I really just want to draw your attention to -- your next sentence, you say, "Exair uses the Novasilk mesh and it's clear and hard to see"; do you see that?

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MR. RUMANEK: Object to the form.
Q The second sentence under your answer.
MR. RUMANEK: Object to the form.
A Under mesh material?
Q Yes.
A Yes --
Q Okay.
A -- to all the above -- oh, okay, I see.
Q And that's consistent with the other document we saw that said you're using PROLIFT and Exair about 50/50 of the time, right?
A Correct.
Q Right. And we were discussing some of the attributes of Novasilk, or Exair, right? And this appears to confirm what you were just testifying to, that's all I'm talking about.
MR. RUMANEK: Object to the form.
Q But you continue down in that, it says, "The stiffness to it is better to discern the patient tissues from the graft itself." And there you're talking about the PROLIFT or Gynemesh mesh, which is stiffer, right?
A Correct.
MR. RUMANEK: Object to the form.
Q And you note that you have an awareness of

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it, where you are, which you're just saying you have better handling, you can -- you know what's going on with the mesh better because if it's stiffer, right?
MR. RUMANEK: Object to the form.
A Correct.
Q "But from the patient side, it can be noticed from the male side. It becomes an issue if it is exposed"; do you see that?
A Correct.
Q And you finish, "It is a known risk as an exposure if you are sexually active"; do you see that?
MR. RUMANEK: Object to the form.
A Correct, I see that.
Q And these two meshes have different stiffness, right?
A Correct.
Q One of the aspects of the design of any given mesh is the pore size is going to be different, right?
A Correct.
Q And the geometry or pore configuration is going to create a different stiffness of each mesh?
A Right.
Q It's going to probably have a different

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elongation profile, correct?
A Correct.
Q Different -- it stretches differently, correct?
A Correct.
Q And just simply, the Novasilk mesh that you used in the product, you helped to design, had a different mesh construction as compared to the Gynemesh, right?
A Correct.
Q And the Gynemesh mesh used in the PROLIFT is a little stiffer, right?
A Correct.
Q And you liked the stiffer mesh because it was easier to handle when you're implanting, correct?
A Correct.
Q But you note here that the stiffer mesh can be noticed by the male side and it becomes an issue if it's exposed, correct?
MR. RUMANEK: Object to the form.
A It can be noticed if it's exposed during sexual activity, correct.
Q Right. It's stiffer, you're going to feel it more likely as opposed to a softer mesh; is that

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correct?
MR. BENTLEY: Object to the form.
A Not necessarily.
Q Well, you state here that, "from the patient side, it can be noticed from the male side"?
MR. RUMANEK: Object to the form.
Q That's what it says here, right?
A But any mesh exposure can be noticed.
Q Right. But you note it here that the PROLIFT is stiffer, right?
MR. RUMANEK: Object to the form.
A Right.
Q And you note that, "From the patient side, it can be noticed from the male side, it becomes an issue if it is exposed," you noted, right?
MR. RUMANEK: Object to the form.
A If -- well, there are a lot of asymptomatic exposures, so it could potentially -- any mesh exposure could be symptomatic or asymptomatic.
Q Right. And a softer mesh, you're not going to notice it as easily as a stiffer mesh, generally, right?
MR. RUMANEK: Object to the form.
A It depends on where the exposure is.

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Q Right. I mean, if -- all things equal, a softer mesh you're not going to notice as much if it's exposed during sexual intercourse, that's all you're noting here, right?
MR. RUMANEK: Object to the form. It mischaracterizes the testimony.
A It depends on the circumstance.
Q Well, I'm trying to understand what your words say here, Doctor. And I get that everything is different, circumstances are different, patients are different, but just generally, you're talking about PROLIFT is stiffer than Novasilk, right?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. And you're saying that there's a difference if it exposes just because it's stiffer, right?
MR. RUMANEK: Object to the form.
A No, I'm not saying that at all.
Q Then explain what you're saying here when you're pointing out that the patient can notice it from the male side.
MR. RUMANEK: Object to the form. Asked and answered.
A If there's any mesh exposure, regardless

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of the type of mesh, it can be noticed on the male side depending on the circumstances.
Q And here you're talking about the stiffness differences of the two meshes, right?
MR. RUMANEK: Object to the form.
A I'm saying my perception is that the Gynemesh is stiffer --
Q Right.
A -- and so I would assume that there may be a difference, but it's -- clinically speaking, it doesn't always play out that way.
Q Well, it's stiffer, we know that, right? It's stiff -- the PROLIFT mesh is stiffer than Novasilk, right?
A Correct.
Q Right. And there's a couple of things that are -- that that stiffness creates that are different. One of them is you have better handling during implantation, right?
A Agree.
Q And you just said it, potentially you might notice it more as compared to a softer mesh, right?
MR. RUMANEK: Object to the form. Mischaracterizes the testimony.

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A Correct.
Q Did you originally approach Ethicon or J&J with the Exair before you took it -- before you consulted with Coloplast to design it?
A Yes.
Q Do you remember why they didn't pursue your product, why Ethicon didn't pursue your product?
MR. RUMANEK: Object to the form.
A I don't know why they ultimately didn't pursue it, but one of their concerns was that the -- the trocar pass from the Exair may be more -- may compromise the neurovascular bundle, Alcock's canal, more so than their technique.
Q And that's -- is that referring to your, like, procedural customization of the PROLIFT?
A Correct. Correct.
Q But in your experience, you didn't perceive any increased problems with using your customized PROLIFT technique, right?
A Correct.
Q In fact, you had better results with it?
MR. RUMANEK: Object to the form.
Q Let me rephrase it. In fact, your customized -- with your customized PROLIFT

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technique, you had better success rates with the patients you implanted the mesh, right?
MR. RUMANEK: Object to the form.
A I believe so.
Q Doctor, I'm handing you what's being marked as Exhibit 10. It's another Coloplast document I pulled off their website. Do you think you ever reviewed one of the Coloplast patient brochures with the patients that you were implanting the Exair product in?
(Exhibit 10 was marked for identification.)
A No, I did not.
Q Would you have given your patients -- I'm sorry, are you done?
A I had these brochures, but I didn't specifically go over it with them.
Q You had product brochures for like all the products that you were offering patients; is that fair?
MR. RUMANEK: Object to the form.
Q Let me say, was it your -- if the sales rep gave you brochures to go to patients for the products you were implanting, you would have given those to your patients?

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MR. RUMANEK: Object to the form.
A They were available, but I didn't specifically give it to them.
Q You didn't affirmatively recommend that the patients should review the brochure?
A I would review the technique and my risks and benefits, so -- I have with them, but I didn't always have these things around, so I may give it to them if it was available.
Q Sure. But it could be a useful tool for educating the patient about for the surgery they're going to undergo; is that fair? In addition to your discussion, of course, correct?
MR. RUMANEK: You got to let me -- you got to let him answer the question.
A Yes, I think that my discussion and my perception and experience were really what I based my counseling on, and this was purely a supplement.
Q And you had very detailed discussions with your patients about the risks and benefits of these procedures, right?
A Correct.
Q How long would those consent discussions usually last?
MR. RUMANEK: Object to the form.

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A Depends. Anywhere from ten to 20 minutes.
Q Were your discussions longer regarding patient counseling on mesh procedures as opposed to other procedures?
A Yeah, there was more things to cover, correct.
Q Would you have described it as very time consuming to counsel patients on mesh procedures?
MR. RUMANEK: Object to the form.
A Over a period of time, it became more time consuming.
Q You know that that was appropriate in your opinion, to fully educate the patients on a procedure they were undergoing, right?
MR. RUMANEK: Object to the form.
A It was in the basis of, you know, common risks or things that I saw specific to that patient, correct.
Q And, Doctor, if you could turn your attention on Exhibit 10 to page 9. I just want to see if you agree with some of these statements. I acknowledge this is obviously not an Ethicon product brochure. You see at the top, it says, "Are there any risks with mesh?"
A Correct.

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Q And the second paragraph, the -- I guess the third sentence says, "Potential complications from mesh surgery may include: pain, slow healing of mesh infection or non-healing, mesh extrusion from the vagina, mesh erosion into adjacent organs, nerve injury, recurrent prolapse, inflammation, adhesion formation, fistula formation, narrowing of the vagina, scarring, pain with intercourse, and mesh contraction." And my question is, would you agree that those are all potential complications from mesh surgery like PROLIFT?
MR. RUMANEK: Object to form.
A I think from any surgery.
Q And so you would agree that those are all potential complications from mesh surgery?
A Let's see. Yes.
Q And you were discussing that, of course, all procedures have --
A Well, I take that back.
MR. RUMANEK: Hold on.
A Infection, I don't see that as being clinically significant in terms of what I've come across.
Q And the next paragraph, I think, addresses what you were discussing, that, in fact, all

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procedures have some complications, right, just generally; is that fair?
A Correct.
Q And as -- and this next sentence states, "As with any surgery, other potential complications can include bleeding, infection, injury to blood vessels and nerves, bladder, urethra, or bowel injury during mesh placement and may require additional surgery to repair." And you would agree that other potential complications can include those things, correct?
A Correct.
Q And here it's just differentiating between mesh complications and stuff that are just generally potential complications of any surgery; is that fair?
MR. RUMANEK: Object to the form.
A I would say that, you know, not necessarily. I mean, I'd say the biggest difference between the general -- generalized surgery and a mesh-based surgery would be mesh exposure.
Q Well, what about -- so let's have it defined, mesh exposure, are you talking about extrusion to the vagina or are you talking about mesh exposure in the organs?

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A Both.
Q So you're just using erosion interchangeably?
A Correct.
Q Everyone is a little different?
A Correct.
Q What about mesh contraction, is that a complication that's specific to a mesh implant?
MR. RUMANEK: Object to the form.
A Correct.
Q Just change gears a little bit, Doctor. Your report lays out your qualifications based on your education and experience, and my question is, you're not holding yourself out as an expert in the design of biomaterials, are you?
MR. RUMANEK: Object to the form.
A Correct.
Q Because, as you said, you didn't design the Novasilk in the -- mesh in the Exair product because you don't design meshes; is that --
MR. RUMANEK: Object to the form.
A Correct.
Q And you're not holding yourself out as an expert in epidemiology or statistical analyses, right?

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MR. RUMANEK: Object to the form.
A Correct.
Q Right. Because even with your database, you get the statistician to do the number-crunching because that's not in your purview, right?
MR. RUMANEK: Object to the form.
A Correct.
Q And you're not holding yourself out as an expert in pathology analysis, are you?
MR. RUMANEK: Object to the form.
A Not in the general, but --
Q Have --
MR. RUMANEK: Hold up. Let him answer the question.
A -- but, you know, more specifically to things having to do with my field.
Q Sure. And if you excised, or removed, some mesh after a woman who underwent a procedure and had mesh implanted to treat prolapse, if you removed some mesh, would you then send that mesh off for a pathologic review?
A Typically not. It would be a gross submission of products.
Q And so you wouldn't -- I just want to be clear, you yourself wouldn't do some sort of

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pathological review of the specimen other than just the gross examination; is that correct?
MR. RUMANEK: Object to the form.
A Correct.
Q So you never looked at the mesh under a microscope, correct?
A Correct.
Q And you never looked under a -- I think a scanning electron microscope either, correct?
A Correct.
Q Right. And you would sometimes -- or would you sometimes send the mesh specimen, the explanted mesh specimen, to the pathologist to look at?
A Only if it was requested by the patient.
Q How many times -- do you have an idea of how many times you've had a patient request that such that you've sent the mesh to a pathologist?
A Typically it was if they're involved in some litigation, they would ask for it to be sent.
Q And would you request any specific pathological -- would you request any specific tests that the pathology department perform on the explanted mesh?
A No.

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Q You would just -- whatever they felt was appropriate testing, you would defer to them; is that --
MR. RUMANEK: Object to the form.
A Correct.
Q Doctor, you're not holding yourself out as an expert in FDA regulations generally, are you?
A Correct.
Q Right. Correct, you're not, right?
A Correct, not.
Q And you're also not holding yourself out as an expert in the regulations or requirements regarding instructions for use drafting, are you?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. And you're not an expert in medical device industry practices, right?
MR. RUMANEK: Object to the form.
A Correct.
Q You're not -- well, you've done some design of the medical device for Coloplast and the Exair product, so are you holding yourself out as an expert in the design control processes with regard to medical devices?
A The design control processes?

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MR. RUMANEK: Object to the form.
Q Right.
A No.
Q When you were helping design the Coloplast pro- -- the Coloplast Exair product, that was really you as a clinician giving your input into how the procedure should go --
MR. RUMANEK: Object to the form.
Q -- is that correct?
A More or less, correct.
Q Rather than how -- the design requirements matrix versus the risks versus how all that stuff goes together, you're not involving yourself in the actual design process from the medical manufacturer --
MR. RUMANEK: Object to the form.
Q -- is that correct?
A Correct.
Q You're not an expert in drafting the adverse of insections for instructions of use, are you?
MR. RUMANEK: Object to the form.
A Correct.
Q Right. You're -- well, have you reviewed Ethicon's internal design processes?

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A No.
Q They're really long.
Did you review the -- what's called the DFMEA, or the Design Failure Modes Effects Analysis, that was created for PROLIFT?
A Not that I recall.
Q That's a very long document.
A A very long document, I'm sure.
Q And also you didn't review the DDSA, or -- I can't remember what that stands for. Do you recall reviewing the DDSA --
MR. RUMANEK: Object to the form.
A No.
Q -- another design document?
A No, I don't.
Q And you didn't review Ethicon's internal protocols for design, you didn't review their DFMEA or DDSA, so you don't know if Ethicon actually met its own standards regarding its requirements for design control, do you?
MR. RUMANEK: Object to form.
A Well, I reviewed, you know, what's in the list in general, so I can't say specifically I recall these, but no, I don't.
Q And last, you're not an expert in

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corporate conduct or industry practices, are you?
MR. RUMANEK: Object to the form.
A No, I'm not.
Q Doctor, I'd like to talk a little bit about your personal definitions of some things here, and you may not have answers to some of them, fine -- which is totally fine, but do you have an opinion as to what you think or what you intend to testify to the jury as to what the true success rate is for the PROLIFT device?
MR. RUMANEK: Object to the form.
A The true success rate?
Q Right. Or what -- there's a wide variety of different numbers out there in the literature, correct, and you're in part relying upon the literature that you reviewed, right?
A Correct.
Q And in part you're relying upon your own experience, correct?
A That's correct.
Q And I'm just asking, based off your review of the literature and based off your personal experience, do you intend to testify to the jury as to a specific percentage success rate for women that undergo an implant procedure with the PROLIFT

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device?
MR. RUMANEK: Object to the form.
A When you say "success," can you be specific as to what you --
Q Sure. I mean, if there's some ways that you'd want to -- it would be easier for you to give me some numbers, if you intend to discuss numbers. I just don't know if that is your intention.
MR. RUMANEK: Let me just -- there's a whole lot of numbers in his -- are you saying outside of what's already contained in his report?
Q Yeah, outside of just citing a bunch of studies and findings, which there's a lot of them, do you have any, like, after reviewing 20 studies, I'm deciding that the success rate is 11 percent, or have you made any type of calculation?
MR. RUMANEK: That would be a really low success rate. Sorry.
Q Or 11 percent failure.
A Right. Right. You know, my -- what I counsel people on is what I would -- my answer would be, and that's based on my personal experience, which has been in general around a 94 to 96 percent success rate with using the transvaginal mesh.

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Q And how are you -- I'm sorry, how are you defining success when you talk to your patients?
A Success based on my database is lack of recurrent prolapse.
Q Total lack?
A Lack of prolapse that the patient perceives is one of the things I'm looking at and lack of prolapse beyond the introitus.
Q And those are different data points in your database?
A Correct.
Q And so when you're counseling patients, you're primarily giving them information based upon your review of your database?
A Correct.
Q And you've also reviewed literature, but your primary basis for your counseling is your personal experience; is that correct?
MR. RUMANEK: Object to the form.
A Correct.
Q And similarly, do you -- I would assume your database has data points for complications; is that correct?
A Correct.
Q And does your database track erosion

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separately?
A Correct.
Q Does it track dyspareunia separately?
A Correct.
Q Are you -- is your database tracking de novo versus pre-existing dyspareunia?
A Correct.
Q So those are separate data paints?
A Correct.
Q And is your database tracking chronic vaginal pain?
A No.
Q Is your database tracking chronic pelvic pain?
A No.
Q So when you're counseling patients, you're going to -- is it fair to say you're going to discuss erosions, expected erosion, expected dyspareunia, the potential for those things happening based upon your personal experience as based on your experience documented in your database, is that generally what's happening?
MR. RUMANEK: Object to the form.
A Correct.
Q And then I would assume you're also

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discussing the potential for chronic vaginal pain and chronic pelvic pain with patients also, right?
A With any surgery, correct.
Q Sure. But you don't have any data in your database to provide a basis for you to give like a description of what you expect to the patients, just solely based on your database? You don't have that information, right?
MR. RUMANEK: Object to the form.
A Specific to --
Q That was a horrible question.
So your discussion with patients, you know, is obviously going to involve all the potential complications of the implant, right?
MR. RUMANEK: Object to the form.
A No.
Q Well, it's going to -- your discussion with patients is going to involve the potential complications associated with the PROLIFT device, correct?
MR. RUMANEK: Object to the form.
A Correct.
Q And those would include potentially erosion, dyspareunia, vaginal pain, and pelvic pain, correct?

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A Correct.
Q And the basis for the information that you're going to provide the patients when you're counseling them for erosion and dyspareunia is data points that you have in your database, right?
MR. RUMANEK: Object to the form.
A Correct.
Q And your database just doesn't have data points for the vaginal pain and pelvic pain, right?
A Correct.
Q So at that point you're relying upon your general experience and the literature to discuss those potential complications with patients; is that correct?
MR. RUMANEK: Object to the form.
A It's more of a specific, you know, blanket counseling that any pelvic surgery can result in chronic pain that can be intractable.
Q So you don't have any type of estimate as to how often chronic vaginal pain occurs after implantation of PROLIFT?
MR. RUMANEK: Object to the form.
A Correct.
Q And similarly, you don't have an estimate based -- of -- you don't have an estimate of how

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often chronic pelvic pain might happen to a woman after implantation of a PROLIFT; is that correct?
MR. RUMANEK: Object to the form.
A Say it one more time. I don't have an estimate.
Q You don't provide an estimate or have any type of estimate of the chronic -- of chronic pelvic pain associated with PROLIFT, do you?
MR. RUMANEK: From his database or are you --
MR. BENTLEY: From anything.
MR. RUMANEK: Object to form.
A No, I don't give them a specific number.
Q Do you give them specific numbers for the rate of erosion and dyspareunia?
A I give them a specific number for rate of erosion.
Q Does your database track the reoperations?
A I'm trying to think whether -- there is some notation there of reoperations, but it's not -- I can't say there's specific data points for that. It's in the comments.
Q And I guess if you don't have a data point for reoperation, you're not going to have a data point for how often they had to have a reoperation

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for recurrence of prolapse; is that fair?
MR. RUMANEK: Object to the form.
A Well, I mean, that's a tricky question because, you know, you can have prolapse in a different compartment, which is a new type of prolapse, versus recurrent prolapse. So I am tracking both new prolapse, recurrent prolapse, but I don't have a specific number for the number of people who actually are symptomatic from any of these things who choose to have something done.
Q Well, I mean, if you treated another compartment of prolapse with mesh, that would -- that would show up in your database again, right?
A Correct. Correct.
Q Right. And does your database have data points tracking reoperation for complications?
A There's a notation in there but not a specific column that I have.
Q And when you counsel patients who are undergoing -- or who are choosing to undergo a PROLIFT procedure, you're discussing the risks and benefits, would you discuss with them the rates of reoperation?
MR. RUMANEK: Object to the form.
A No, I really don't make a specific number.

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I just say in general, there's a risk of failure.
Q Like there is with any surgery --
A Right.
Q -- surgery, right?
A Correct.
Q And I'm going to ask you similar questions with regard to native tissue repair, okay?
A Sure.
Q Do you have an opinion as to what the overall success rate is for patients that undergo a native tissue repair to treat prolapse?
A Just solely based on the literature, reoperation rates vary tremendously because, again, it's very subjective. In general, I think the most commonly quoted statistic ranges around -- I'm trying to remember exactly. I tell patients in general, there's a 30 to 50 percent rate of failure with native tissue repair.
Q And that's considerably higher than your opinion as to the success rate with PROLIFT -- let me rephrase that.
A 30 to 50 percent failure rate is considerably higher than your experience and opinion as to what the failure rate is with the PROLIFT; is that correct?

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A Correct.
Q And you -- as we discussed, you don't track native tissue repair in a database, correct?
A Correct.
Q So you're relying upon the literature, correct?
MR. RUMANEK: Object to the form.
A I'm relying upon my clinical experience subjectively --
Q Sure.
A -- and the literature, correct.
Q To present some sort of estimate of failure rates, numerically you're relying upon the literature because you don't keep those numbers; isn't that correct?
MR. RUMANEK: Object to the form. Mischaracterizes his answer.
A I'm relying upon my -- my clinical practice and just the generalized number of a 30 to 50 percent failure rate.
Q How -- do you have some way to numerically evaluate your clinical practice to know how many women you do a native tissue repair on have failure?
A Just from follow-up visits, but nothing tracked in the database, that is correct.

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Q Right. And there's no numerical methodology that you've employed to evaluate your clinical success rate on native tissue repair?
MR. RUMANEK: Object to the form.
A No numeric -- correct, correct.
Q And let's talk about complications with native tissue. It's generally your opinion that complications happen with mesh-based repairs and native tissue repairs as with any surgery, right?
A Correct.
Q But there can be differences in the frequency of complications with different surgeries, right?
A Correct.
Q There could be differences in the frequency of complications with native tissue repair as compared to PROLIFT, right?
A Differences in the frequencies of complications. Different types of complications, but yes.
Q And there can even be differences in the severity of complications from one procedure to another; isn't that correct?
MR. RUMANEK: Object to form.
A Yeah.

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Q For example, if you have a mesh erosion, a serious mesh erosion that's going to require, you know, invasive surgical intervention to excise it, that erosion could be more severe than just a suture eroding, couldn't it?
A Potentially, correct.
Q Do you have an opinion as to what the rate of erosion is, I guess, of sutures with native tissue repair?
MR. RUMANEK: Object to the form.
A Rate of erosion, no, I don't.
Q Do you have an opinion as to what the rate of dyspareunia is with native tissue repair?
MR. RUMANEK: Object to the form.
A It various tremendously.
Q So you don't have an opinion as to --
A Don't have a specific number in mind, no.
Q And do you have an opinion as to what the rate of de novo chronic vaginal pain is after a native tissue repair?
MR. RUMANEK: Object to the form.
A Again, varies tremendously. I don't have a specific number.
Q And do you have an opinion as to what the rate of chronic pelvic pain is after a native tissue

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repair?
MR. RUMANEK: Object to the form.
A Again, same answer, varies tremendously, no specific number.
Q So if you were counseling your patients and discussing a potential native tissue repair and discussing the complications, you wouldn't provide any numerical estimates of the frequency of those complications; is that correct?
MR. RUMANEK: Object to the form.
A Complications being pain?
Q Sure.
A No.
Q Would you provide a numerical estimate of the frequency of chronic vaginal pain with patients if they're deciding to undergo native tissue repair?
A I would just discuss in general it's a risk of any surgery, but nothing different between the mesh and the native tissue.
Q And would you discuss any numerical estimate of the frequency of dyspareunia with native tissue repair?
A Say it one more time.
Q And I'm just trying to get if you discuss any of these estimates -- these frequency estimates

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with patients, and we've gone through I don't think you have an opinion as to what they are. I'm just making sure you don't also tell patients something, okay?
A No. Right, right.
Q When you're counseling patients who are considering undergoing a native tissue repair for prolapse --
A Right.
Q -- do you discuss the frequency -- or what you expect the frequency of dyspareunia to be?
A No.
Q And last, when you're counseling those same patients, do you discuss the frequency or expected frequency of an erosion?
A For a graft repair, correct.
Q But for a native tissue repair, do you discuss the expected frequency of that?
A Well, I tell them that if I'm using permanent sutures, there's the risk of exposure, but I don't have a specific number for that.
Q And what kind of suture do you use?
A For?
Q For -- I'm sorry. When you're doing a native tissue repair, what kind of suture do you

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use?
MR. RUMANEK: Object to the form.
A Typically I use at least one layer of permanent sutures.
Q And do you have any preference as to what specific suture you're using?
A Typically polypropylene or prolene.
Q And that's just like a --
MR. RUMANEK: Hold on a second.
(Off-the-record discussion.)
MR. BENTLEY: Let's just take another break. It's been an hour or so.
MR. RUMANEK: All right.
(Recess from 10:40 a.m. to 10:46 a.m.)
MR. RUMANEK: If you intend to keep the deposition open, my position will be that you've got three hours. If you want to reserve some time to follow back up on certain issues, you can do that.
MR. BENTLEY: I appreciate that. It's hard to follow up on stuff I haven't gotten.
BY MR. BENTLEY:
Q Doctor, we're back from a break. Are you ready to go?
A Yeah.

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Q We were discussing before the break what sutures you use in native tissue repair, and I think you said you used a -- like a single-strand prolene suture; is that fair?
A Correct.
Q And I've seen some discussion in the literature of braided sutures. That's not what you're using for native tissue repair, is it?
A Yeah, sometimes braided tissue -- sutures is what we buy from.
Q Are you using braided sutures in your native tissue repairs?
A Yes.
Q I thought you -- I'm con- -- are you using -- you testified that you used prolene sutures; is that correct?
A Correct.
Q And prolene sutures are not braided, are they?
A Correct. No, no, they're not. They're monofilament.
Q Right. And you testified that when you do native tissue repair that you're using prolene sutures; is that correct?
A I use usually a combination. So I may do

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like a two-layer plication, one layer being synthetic -- I mean monofilament prolene, one layer being monofilament -- I mean multifilament VICRYL.
Q And which layer are you using the multifilament VICRYL for?
A Usually that's -- it varies a lot. Sometimes I'll use it on a deeper layer.
Q Sometimes, so that's not your regular practice, it's in certain circumstances that might dictate that's more appropriate?
A Correct. Correct.
Q What circumstances necessitate you to use a braided suture material?
A Well, if I have a bladder injury and I'm plicating next to that, I may use an absorbable suture named VICRYL in this situation.
Q Is that a braided suture?
A Correct.
Q Okay.
A Correct. I believe it's braided.
Q Well, do you know?
A I'm pretty sure it's braided, yeah.
Q But it's absorbable?
A It's absorbable, correct.
Q And absorbable braided sutures you'll use

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sometimes if there's a bladder injury; is that correct?
A Correct. Closer to like a viscous injury, and then I'll put the permanent layer or the prolene outside of that.
Q So you're going to always use a prolene monofilament suture when you're doing native tissue repair, but there's some circumstances that require you to use like maybe a heavier braided suture like -- or a heavier suture like VICRYL to help reinforce the tissue; is that --
MR. RUMANEK: Object to the form.
Q -- is that correct?
A I use a combination and it depends on the circumstance. I couldn't say always.
Q Sure. So in the general patient that doesn't have bladder injury, you're going to always use the prolene monofilament suture, right?
A No, not at all. I mean, these -- it depends on the circumstances. I mean, sometimes I use VICRYL on people, sometimes I use prolene. It depends on individuals.
Q So those are the -- and those are the two types of sutures you use?
A Sometimes I'll even use GORE-TEX.

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Q And is that a monofilament or a braided suture?
A That is a -- I believe it's a braided suture. It's a permanent suture --
Q Right.
A -- but I think it's braided. It's a -- I think it's -- I don't recall exactly --
Q And, of course, we're not here to guess, you know, so if you don't know, you don't know. That's totally fine.
A I don't know. I know it's a non-absorbable suture.
Q Right. But as you sit here today, you don't know exactly which sutures are braided or not, but you know you do use at least prolene monofilament --
A Correct.
Q -- VICRYL absorbable --
A Correct.
Q -- and sometimes GORE-TEX, correct?
A Correct.
Q All right. Because in your report on -- on page 23, you're discussing that sutures can erode -- if with you're me on page 23. You see at the very bottom, you say, "For example, exposure or

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erosion of permanent sutures or other graft materials can occur with abdominal sacrocolpopexy and other non-mesh procedures with rates as high as 45 percent"; do you see that?
A Correct.
Q And you cite to Toglia? It says Toglia MR after that?
A Oh, yeah.
Q And the title of that article is Suture Erosion Rates and Long-term Surgical Outcomes in Patients Undergoing Sacrospinous Ligament Suspension With Braided Polyester Suture; do you see that?
A Correct.
Q You're -- we discussed you're not sure if you use a braided suture, but do you know if you use a polyester suture?
A I'd have to know the brand name to it to tell you whether it's polyester or not.
Q But you know prolene is not polyester, right?
A Correct.
Q Right. And then you cite to another article there by Yazdany, I guess, you see that, the third citation you have?
A Let's see. Yes.

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Q The title is Suture Complications In A Teaching Institution Among Patients Undergoing Uterosacral Ligament Suspension With Permanent Braided Suture; do you see that?
A Right.
Q So do you have any other evidence to support your contention that 40- -- that erosion of sutures is as high as 45 percent, that that applies to monofilament polypropylene suture that -- like the prolene that you use? Do you have any other evidence to support that?
MR. RUMANEK: Object to the form.
A Okay. I'm not sure I'm understanding --
Q Let me back up a little bit. One of your -- your opinions here is that native tissue repair has the same complications as mesh implants; is that generally correct?
MR. RUMANEK: Object to the form.
A It can have complications.
Q And we discussed one of the unique complications to a mesh implant is that there can be a mesh erosion, right?
A Correct.
Q And here you're saying, well, native tissue repair, you just suture and the sutures can

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erode, right?
A Correct.
Q And here you're trying to estimate or give some -- here you're citing to some studies that show a 45 percent exposure rate of sutures, correct?
MR. RUMANEK: Object to the form.
A Correct.
Q And the studies that you cite to are discussing braided sutures; is that correct?
MR. RUMANEK: Object to the form.
A I believe that -- let me take a look again. It's been a while. Braided polyester suture. Let me just finish this other one. Yes, this is specifically regarding braided suture.
Q And also polyester suture, which is different from polypropylene, right?
A Polyester is different than polypropylene, correct.
Q And my question is, do you have any articles or literature that you can cite -- that you can cite to here to support your proposition that suture erosions with native tissue repairs is 45 percent if it's a monofilament prolene polypropylene suture?
A I didn't cite one.

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MR. RUMANEK: Object to the form.
A I did not cite anything specifically here regarding polypropylene suture.
Q Right. And I agree with that.
A Right. Right. Right.
Q But do you -- as you sit here today, can you cite to anything else --
MR. RUMANEK: Hold on. Hold on. I don't think he was finished with his answer.
A But I can't recall. I've gone through, you know, numerous articles --
Q Sure.
A -- and I don't -- I can't specifically recall anything regarding polypropylene sutures --
Q Right.
A -- in a native tissue repair, erosions with polypropylene suture.
Q Right. And it's not in your report here.
A Right.
Q And as you sit here, you just don't know off the top of your head, right?
A Correct.
Q Doctor, when you're evaluating literature, what are the things that you look for to decide which articles have -- should be given greater

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weight as opposed to other articles?
MR. RUMANEK: Object to the form.
Q I'm assuming you perform that analysis, right?
A Correct.
Q And what are the things you're looking for that would guide your analysis of which articles are more important in reaching your opinions?
A Well, multiple factors. I look at the type of study, you know, the number of participants, the methods involved, the follow-up, so, you know, multiple factors go into it.
Q And you're familiar with the levels of evidence, the Oxford levels of evidence?
A Correct.
Q And do you have an appreciation of what Level 1 evidence is?
A Yes.
Q What's Level 1 evidence?
A Those would be randomized controlled studies perspective.
Q And systematic reviews of --
A Correct.
Q -- of evidence also? And you -- of course, you didn't provide -- or you didn't perform

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a systematic analysis here, did you?
A Of?
Q Let me rephrase it. You didn't perform a meta-analysis or a systematic review of the total literature here, did you?
MR. RUMANEK: Object to the form.
A Correct.
Q You're relying upon the epidemiologists and statisticians that do that, right?
A Correct. I've reviewed a big body of literature and yes, I'm just looking at conclusions and results.
Q Doctor, are you a member of ACOG, or the American College of Obstetricians and Gynecologists?
A Yes.
Q Are you a member of the American Urogynecologic Society?
A Yes.
Q Are those reputable organizations?
A Yes.
Q Are you familiar with Committee Opinion Number 513?
A No, you'd have to show me.
Q Off the top of your head you're not -- it's fair. It's totally fair.

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I'm going to hand you what's being marked as Exhibit 11, and this is Committee Opinion 513 from ACOG and AUS. Are you familiar with that document?
(Exhibit 11 was marked for identification.)
A Yes, I've reviewed it.
Q And this was put out in December 2011; do you see that?
A Yes.
Q And the title of it's Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse; is that correct?
A Correct.
Q And under the Abstract the author states, "Since 2004, use of synthetic mesh has increased in vaginal surgery for the treatment of pelvic organ prolapse, however, concerns exist about the safety and efficacy of transvaginally placed mesh. Based on the current available limited data, although many patients undergoing mesh-augmented vaginal repairs heal well without problems, there seems to be a small but significant group of patients who experience permanent and life-altering sequelae, including pain and dyspareunia from the use of

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vaginal mesh." Did I read that correctly?
A Correct.
Q And you would generally agree with that statement, wouldn't you?
A No, I not necessarily have found that in my practice.
Q But you understand the literature documents women have suffered life-altering complications such as pain and dyspareunia after the implantation of vaginal mesh like PROLIFT? You've seen that literature, right?
A I would say that that's a common complication of any surgery, and they're specifically talking about mesh in this case, but it's a complication.
Q But in your experience your patients seem to be faring better because they haven't suffered these complications as described here; is that correct?
A Not as many, correct.
Q And this kind of goes back to our earlier discussion, some doctors just have different experience levels, expertise, and opportunities to get better, correct?
MR. RUMANEK: Object to the form.

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A Correct.
Q And luckily for your patients, your patients aren't seeing these complications as frequently; is that correct?
MR. RUMANEK: Object to the form.
A Correct.
Q But regardless, ACOG and American Urogynecologic Society issued a committee opinion to highlight that this is an issue, right?
MR. RUMANEK: Object to the form.
A I think that they are making people aware that there can be some complications, but, you know, it's in general. At the same time complications of failure can be just as bad as some of these complications too.
Q Right. And ACOG and American Urogynecologic Society is aware of the complications and failure rates of everything, they had that information in mind when they issued this opinion, wouldn't you assume?
A But they're not specifically addressing that.
Q But they felt it -- or do you -- are you critical of them taking the time to issue this announcement?

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MR. RUMANEK: Object to the form.
A No, I think it's good to be aware that they -- you know, they're bringing this to knowledge, but I think you have to take it in context of the general scheme of what surgery involves.
Q And they're bringing this out to the general knowledge because some doctors just aren't as versed in the literature and the complications as you; is that fair?
MR. RUMANEK: Object to the form.
A Not necessarily.
Q I mean, what's the purpose that you think for them taking the time to write this article?
MR. RUMANEK: Object to the form.
A I think that they have an obligation to explore different surgical techniques and publish their opinions.
Q This is important literature, right?
MR. RUMANEK: Object to the form.
A What specifically?
Q These issues that they're addressing here are very important, right?
MR. RUMANEK: Object to the form.
A I think they are complications, they're

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associated with any surgery, but they are bringing it to light.
Q And that's not a bad thing, is it?
A I think it's important to have some knowledge in the field, but no, I mean, I think there's a good body of evidence that shows that complications are not as -- as prevalent as in some reports as in other reports.
Q And you're -- I think you're talking about maybe the frequency rates; is that --
A Correct.
Q And it looks here that they're not really saying that the frequency is off the charts necessarily, but the abstract just seems to be saying that there's some of these complications that are really severe; is that fair?
A They're saying that there are definitely complications associated with mesh implants, but I think physicians have the knowledge that these complications can occur with any surgery too.
Q And it's important for them to note that there's some complications that are life-altering with these implants?
MR. RUMANEK: Object to the form.
A I think it's more to note that there's

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life-altering complications with any surgical procedure.
Q Yeah, and I'm not talking about any surgical procedure. I'm just asking you in the context -- I appreciate what you're saying, but ACOG went to the time to write this specifically about mesh implants for pelvic organ prolapse, right?
A Correct.
Q And they just thought it's important to get this knowledge out there that some women are having severe complications that are life-altering and we need this information to get out there, right?
MR. RUMANEK: Object to the form.
A Correct.
Q Doctor, if you'd please turn to page 4, and that first paragraph on the top left, they're discussing native tissue rates, and it's similar to what we've discussed today, and -- about -- you see that line that starts "30 to 46 percent" on page 4?
A Correct.
Q And the authors here are noting, "These low success rates were frequently cited as a reason why innovations such as vaginal mesh were needed to decrease failure rates." And that's consistent with

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what you state in your report, right?
MR. RUMANEK: Object to the form.
A Correct.
Q And the authors continue that, "The original data from this study were recently reanalyzed using modern outcome measures, composite of anatomic outcomes and subjective success, and the revised success rates for three arms of this RCT, or randomized clinical trial, were comparable with 89 percent of women having no objective prolapse beyond the hymen"; did I read that correctly?
A You did read it correctly.
Q And you're familiar that they went back and did some reanalysis of the Weber study and found that using modern outcomes, the data from the native tissue repair was better?
MR. RUMANEK: Object to the form.
Q Are you familiar with that literature?
A Yes, I've reviewed that.
Q And do you have any criticisms or reasons to discount the reanalysis of the Weber data using modern outcomes?
MR. RUMANEK: Object to the form.
A Well, again, you know, success is in the eye of the beholder, so, you know, specifically I'd

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have to see that article and look at what they're defining success as.
Q Would you agree that a composite of anatomic outcomes and subjective success is a good way to measure surgical success for treatment of prolapse?
MR. RUMANEK: Object to the form.
A Say it one more time. A composite --
Q Are you familiar with the concept of a composite of anatomic outcomes and subjective success?
A I've heard the term obviously, but, you know, I'd need to see specifically an article or something that you're citing.
Q Okay. Well, we're just looking at the ACOG committee opinion --
A Right.
Q -- and they're mentioning that some scientists went back and looked at the original Weber data, which was -- is often cited for why native tissue repair isn't as successful.
A Right.
Q And that's in part why you state why mesh repairs are important because native tissue repair wasn't very successful, right?

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MR. RUMANEK: Object to the form.
A We just thought that mesh might be more successful.
Q Right. And these authors are merely pointing out that, hey, we've changed the way we look at success, because there's a lot of different ways to look at it, right?
A Correct.
Q And we've gone back and looked at the original Weber data using more modern outcomes, which they're citing here as a composite index, which we'll look at, and just using that, hey, native issue is almost as efficacious as mesh-based repairs. Are you familiar with that literature finding that that's what the Weber study showed using modern outcomes?
A You know, off the top of my head, no, I'd have to look at it specifically.
Q If that was the case, that would be important evidence to look at, right?
MR. RUMANEK: Object to the form.
A Hypothetically speaking, but, you know, I need to see the document and look at the specifics.
Q Sure. But if -- I mean, just generally, if we're relying upon Weber 2001, which uses an

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outdated measurement of success to make clinical decisions, and then we find out that, hey, using more modern outcomes to measure success, that that data is really not so bad, that would be important information to take into account, wouldn't it?

MR. RUMANEK: Object to the form.

A Again, it depends on -- you know, I'm not saying -- it's not necessarily true that the older model of success is any better or worse than the new model. It's just a different model.

Q Sure. And you just want to compare apples to apples, right, generally?

MR. RUMANEK: Object to the form.

A Correct.

Q Right. And if Weber was using one measurement for success and later we've shifted to using a different measurement of success, you would just want to compare them using the same outcome measurements so you can have a fair understanding of what the data really shows? That's fair, right?

MR. RUMANEK: Object to the form.

A Well, again, I'd need to see a specific article with what we're measuring as success because I don't -- you know, if you can show me something, I can read through it and look at what their

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methodology was and what they're defining, then I could better answer your question.

Q But you're relying upon the original Weber data that showed that native tissue repair was not very successful, though, right?

A I'm relying --

MR. RUMANEK: Object to the form.

A I'm relying upon not specifically one piece of information, but the literature in general as well as my own clinical experience.

Q Well, your clinical experience doesn't numerically track native tissue repair, right?

MR. RUMANEK: Object to the form. Asked and answered.

A Correct, it does not specifically track that.

Q A little bit farther down on that page, there's a section titled Who Are The Best Patients For Transvaginally Placed Mesh; do you see that?

A Yes.

Q And we've discussed this, that not every patient is appropriate for every surgical treatment, right?

A Yes.

Q And you would agree that PROLIFT is not

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necessarily appropriate for every patient, right?

A Correct.

Q And that's an important analysis for you as the physician to undertake to decide with this specific patient, what is the appropriate treatment method for that patient, right?

A Correct.

Q And these authors here, the second sentence, they state, "Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risks, such as individuals with recurrent prolapse (particularly of anterior compartment), or with medical co-morbidities that preclude more invasive and lengthier open and endoscopic procedures"; did I read that correctly?

A You did.

Q And would you agree with that statement, Doctor?

MR. RUMANEK: Object to the form.

A I would say that over a period of time, the thought process has evolved that mesh is not necessarily indicated for initial repair, but, you know, it's more focused now on recurrences.

Q So you would agree with that statement,

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that mesh should be reserved for high-risk patients such as failure, patients that have undergone previous surgery and failed and had recurrent --

MR. RUMANEK: Object to the form. Mischaracterizes his testimony.

A No, I don't think that's accurate because I still use it as a primary repair or have used it too as a primary repair, so I wouldn't think a blanket statement --

Q So let's break it down a little bit.

MR. RUMANEK: Why don't you hold on. He didn't finish his answer.

A Yeah, I don't think a blanket statement necessarily is law.

Q Okay. You just repeated. Thanks.

MR. RUMANEK: No, actually you cut him off. He was in the middle of a sentence and you cut him off.

Q Let's talk about it. You don't think -- or, first of all, do you agree or disagree with the statement -- with the recommendation put out by ACOG and AUS, who you're a member of, do you agree with their recommendation for who the appropriate patients are for mesh-based repair?

MR. RUMANEK: Object to the form. Asked

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and answered.
A Do I agree with the recommendation? I agree that it definitely needs to be taken into account, but I don't think it is a hard and fast answer.
Q And you think PROLIFT is going to be appropriate when a patient has failed an initial surgery? That's one patient population where it could be appropriate to use a PROLIFT, when they've failed a previous surgery, right?
MR. RUMANEK: Object to the form.
A It could be.
Q And you testified that it could also be an appropriate treatment as a primary surgery for patients who have poor tissue quality; is that correct?
A Correct.
Q Right. Which is largely consistent with the recommendation of these committees, right?
MR. RUMANEK: Object to the form.
A In general.
Q Doctor, are you familiar with the Cochrane Group?
A Yes.
Q Is that a reputable organization?

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A Yes.
Q They put out very extensive literature reviews?
A They do.
Q And they spend a lot of time reviewing a lot of literature and doing numerical analyses of a vast body of literature; isn't that fair?
A Correct.
Q That's kind of their expertise --
A Correct.
Q -- right?
And you rely upon reviews done by the Cochrane Group in reaching your opinions here, correct?
A It's part of what goes into my opinions.
Q And they're listed on your reliance list, correct?
A Correct.
Q And you cite to a lot of them in your report even, right?
A I do.
Q And one of the Cochrane Reviews that you cite to in your report is the 2016 Maher article. You're familiar with that article, right?
A Not off the top of my head.

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Q I'm handing you what's being marked as Exhibit 12, which is a very lengthy --
MR. RUMANEK: There's a summary.
Q We'll go to the summary. And this article is titled Transvaginal Mesh Or Grafts Compared With Native Tissue Repair For Vaginal Prolapse (Review); do you see that?
(Exhibit 12 was marked for identification.)
A Yes.
Q And this is --
A 2016.
Q -- 2016, okay. And we were discussing the levels of evidence, and this is a systematic review or the highest level of evidence, right?
A Correct.
Q And let's look under -- on page 1 there's an abstract, page 1, page -- yeah, it will start --
A Yeah, okay.
Q And the title is Transvaginal Mesh Or Grafts Compared With Native Tissue Repair For Vaginal Prolapse; do you see that?
A Yes.
Q And that's addressing the issue -- the issues that we've been discussing here today; isn't

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that correct?
MR. RUMANEK: Object to the form.
A Yes.
Q And down in the abstract, you can see the objective is listed as, "to determine the safety and effectiveness of transvaginal mesh or biological grafts compared to native tissue repair for vaginal prolapse." Did I read that correctly? Yeah, I'm still in the abstract.
A Yeah.
Q And --
MR. RUMANEK: He's right here.
Q Just under the abstract. I'm just going to go over the methodology briefly. They state that they searched the Cochrane register, the MEDLINE, and looked at journals and talked to authors. Generally they're just documenting that they did a fairly extensive search of the body of literature, would you agree with that?
MR. RUMANEK: Object to the form. It speaks for itself.
A Agreed.
Q And, in fact, they -- their selection criteria, they note that they only looked at randomized controlled trials; do you see that?

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A Yes.
Q And so they performed a systematic analysis and only evaluated RCTs; is that fair?
A As it states, correct.
Q And under Main Results, they note that they included 37 RCTs comprising of 4,023 women; do you see that?
A Yes.
Q Would you agree that's a fairly large number of RCTs?
A Yes.
Q If you could turn your attention to page 2 under Authors' Conclusions, this -- the authors, Chris Maher and everybody, summarized their conclusions that are fairly detailed in 138 pages in this literature review, which I won't take you through, but --
A You want to go through the whole --
Q No. So their conclusion they state, "While transvaginal permanent mesh is associated with lower rates of awareness of prolapse, reoperation for prolapse and prolapse on examination than native tissue repair is also associated with higher rates of reoperation for prolapse stress urinary incontinence or mesh exposure and higher

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rates of bladder injury at surgery and de novo stress urinary incontinence." Did I read that correctly?
A Correct.
Q They continue, "The risk/benefit profile means that transvaginal mesh has limited utility in primary surgery"; do you see that?
A Yes.
Q And that's kind of in line with the ACOG Committee Opinion 513 that we were just discussing; is that correct?
MR. RUMANEK: Object to the form.
A They mention that it should be looked more so for higher-risk surgery, correct, but it didn't exclude using it.
Q And they're not -- to be fair, they're not saying it should be excluded entirely here, right?
A Correct.
Q They're just saying it has limited use in primary surgery, right?
A Correct.
Q And they continue, "While it's possible that in women with higher risk of recurrence, the benefits may outweigh the risks, there is currently no evidence to support this position"; do you see

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that?
A Yes.
Q And do you agree with that statement?
A My personal experience doesn't dictate the same.
Q And let's break it down. You would agree that there's no evidence to support that position, but your personal experience is slightly different; is that correct?
MR. RUMANEK: Object to the form. Mischaracterizes his testimony.
A I would say that, you know, in reviewing the broad body of literature, there is definitely articles that support the benefits of mesh. Their conclusion is their conclusion, but there are definitely articles that support and go against the use of mesh.
Q So you disagree with the -- that sentence from the Cochrane Review that we just read?
A Well, it's their conclusion. I don't -- I mean, personally I have not seen that and I think there's literature that supports it, but their random -- their review is what they stated.
Q So you agree that they reviewed 37 RCTs, right?

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A Correct.
Q And based off that review, this is the conclusion they came to, right?
A This is their conclusion.
Q And we don't doubt the methodology that the Cochrane Group undertook to review literature, right?
MR. RUMANEK: Object to the form.
Q Do you have a criticism of the methodology the Cochrane Group undertook to review the 37 RCTs?
A No, I don't.
Q And you would probably defer to their expertise in crunching the numbers here, right?
MR. RUMANEK: Object to the form.
A Yes.
Q And do you have any criticisms or reasons to discount the analysis they undertook in performing this review?
MR. RUMANEK: Object to the form. Asked and answered.
A Yes, I think that, you know, a lot of studies they reviewed may not necessarily have conclusions that I would necessarily agree with, but it's part of the randomized control of studies. So as a whole, they're looking at this answer, but

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individually taken, I don't necessarily agree with it.
Q So let me make sure I understand. You don't have any criticisms of the methodology employed by Maher and the Cochrane Review in doing the analysis, their methodology specifically, right?
A I don't know their --
MR. RUMANEK: Object to the form.
A I have not reviewed their methodology.
Q But you do have some disagreement or reason to doubt some of the studies they included in their systematic review; is that correct?
MR. RUMANEK: Object to the form. Mischaracterizes his testimony.
A I would say that there's many studies that support and refute their conclusion, and you'd have to go study by study, but I just don't necessarily think that, clinically speaking, this necessarily represents the broad body of literature that I like, that I look at nor in my own clinical practice.
Q You would agree that they went and looked at the study level, the strengths and weaknesses of each of the studies they included, you know they did that, right?
A If you say so. I didn't specifically read

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the methodology of this, but I'd assume they did.
Q Right. I mean, you would assume that they undertook a fairly detailed analysis, it's 139 pages, right?
A Correct.
Q And you -- in your report, you cite to this Cochrane Review, don't you?
A Yes.
Q But you don't discuss the authors' conclusions that mesh like PROLIFT should be reserved for high-risk patients, do you?
A I don't believe I specifically stated that.
Q Right. And you don't also discuss the conclusion that it should be -- that PROLIFT has limited use in primary surgery, right?
MR. RUMANEK: Object to the form.
A I don't believe I specifically stated that, correct.
Q And similarly, you don't discuss the ACOG Committee Opinion 513 recommendations that's in line with the Cochrane conclusions?
MR. RUMANEK: Object to the form.
A I don't specifically point that out, correct.

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Q But in your report, you do discuss literature, right --
A Yes.
Q -- that supports your opinions, right?
A Correct. Some of it does, some of it doesn't.
Q But just not the Cochrane 2016 review, right?
MR. RUMANEK: Object to the form. He does cite to the Cochrane 2016 report.
Q Let me rephrase it. You discuss the Cochrane 2016 in your report, but you don't discuss their conclusions that are contrary to your opinions here, do you?
MR. RUMANEK: Object to the form.
A Not specifically, correct.
Q And so as you sit here today, you've testified that you disagree with some of the studies that they included in their analysis, right?
MR. RUMANEK: Object to the form. Mischaracterizes his testimony.
A I would say that they probably included studies that I may agree or disagree with, but I specifically haven't looked at each individual study to see what they did here, you know.

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Q Well, like the Cochrane Group did, you haven't done that analysis, right?
A I've not done their analysis, correct.
Q Right. And other than -- I understand that criticism of the Cochrane analysis. Other than that --
MR. RUMANEK: Hold on. I don't think that's --
MR. BENTLEY: I haven't asked the question. But, Counsel --
MR. RUMANEK: Okay. Go ahead.
Q Other than that critique, if you will, of -- or reason for discounting the Cochrane's conclusions, do you have any other qualms with the methodology they employed or anything else they did?
MR. RUMANEK: Object to the form. Mischaracterizes his testimony.
A I -- you know, again, I can't say that I looked through their entire methodology, but their conclusion is their conclusion, you know. And the literature is very broad, and I don't think it necessarily reflects my clinical experience.
Q All right. A lot of the studies that the -- well, obviously your clinical experience is different than the literature to some extent, right?

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A Some of it, right.
Q I mean, you actually might be doing better than a lot of other doctors out there; is that fair?
A I might.
Q And so maybe the clinical experience of other doctors is better documented in the literature, the Cochrane Review; is that correct?
MR. RUMANEK: Object to the form.
A I don't understand the clinical --
Q I don't really understand what that was either. Withdrawn. I'll give you that.
Doctor, if you'd turn to page 25.
A Of?
Q Your report, I'm sorry. You can put that aside.
On page 25, there's a pretty long paragraph. About half of the way through on the right side, you state -- you note the Cochrane Review. I don't know how else to --
A Okay.
Q I'll represent to you that I think this is the one sentence in your report that cites the 2016 Cochrane Review. You state, "The Cochrane Review has reported similar findings that there was no increase rate of dyspareunia with transvaginal mesh

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augmentation compared to traditional prolapse repair without mesh"; do you see that?
A Yes.
Q And my question is just simply, we looked at the Cochrane Review, and the authors have many findings and conclusions in addition to that one sentence that you discuss in your report, right?
A Correct.
Q Okay.
A You know, I've taken those into account, obviously reviewing them, and this is what I've put in my report.
Q But they're not -- you don't discuss their conclusions anywhere in your report, though, right?
A Well, this is a specific chapter on -- or section on dyspareunia and mesh contracture, and so I simply --
Q Right.
A -- put their findings --
Q Okay. Well --
A -- which reflect my clinical beliefs.
Q Got it. So the authors really were looking at the success rates of PROLIFT compared -- or the authors of the Cochrane 2016 Review were really looking at mesh-based repairs versus native

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tissue repair and the success rates, right?
MR. RUMANEK: Object --
A Correct.
Q Which that's an issue covered in your report, right?
A Yes.
Q Right. And you cite the 2016 Cochrane Review in your report --
A Correct.
Q -- but not under this section talking about the efficacy of native tissue repair, right?
A I don't know. Let me look and see. I don't know what section it was.
Q If you want to turn to page 13, you start talking about native tissue repair, surgical results.
A Okay.
Q So you start on page 13, "He notes that the Altman study, the Benson study, the Whiteside study"; you see those?
A Yes.
Q And those studies were included in the analysis of the 2016 Cochrane Review, right?
A I don't specifically know.
Q But if they included all of those, you

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wouldn't be surprised, right?
A No, I would not.
Q And on the next page, you cite to Maher 2008; you see that?
A Correct.
Q And that's eight years before the 2016 Cochrane Review we were just looking at, right?
A Correct.
Q Right. And to be fair, Maher and the Cochrane Group continued to put out Cochrane Reviews as more data was available, right?
A Correct.
Q And the 2016 review that we were just looking at is the most current complete review of the entire literature body, right, by the Cochrane Group?
A Yeah, as I'm aware, correct.
Q That next paragraph you cite to Maher 2013; do you see that?
A Yes, it's written 2013, yeah.
Q And that's for the proposition that "anterior repairs associated with more prolapse than" -- "the native tissue anterior repair was associated with more prolapse than polypropylene mesh"; is that correct?

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A Correct.
Q Right. And three years later, the 2016 review changes course, right?
MR. RUMANEK: Object to the form. Completely mischaracterizes the evidence.
A They're talking about -- well, what's he talking about? 2016 --
Q The title of the 2016 was Transvaginal Mesh Or Grafts Compared With Native Tissue Repair For Vaginal Prolapse, right?
A Yeah, let me look back at their conclusion here. Actually it still says, "The transvaginal mesh is associated with lower rates of awareness of prolapse and reoperation of prolapse and prolapse on examination than native tissue repair."
Q Right. And they conclude that, "Based upon the risks and benefits, that the risk/benefit profile does not support the use of mesh," right?
MR. RUMANEK: Object to the form. Mischaracterizes the evidence.
A Correct. This is the generalized statement.
Q Right. So they're taking into account the literature that they looked at in 2013 and they've come to a conclusion that it's not appropriate in

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2016, right?
MR. RUMANEK: Object to the form.
A No, not at all.
Q You think that in 2016 they're recommending the use of mesh like PROLIFT for primary repair?
MR. RUMANEK: Object to the form.
A They basically said that there's a lower evidence -- rates of awareness of prolapse, reoperation for prolapse, and perhaps on examination, the native tissue repair. That doesn't say don't use mesh. There's a benefit.
Q In 2016, to be clear, the authors are saying mesh has limited utility in primary surgery, you would agree with that?
A That's what they're saying.
Q And you -- your opinion today is that you agree that PROLIFT has limited use in primary surgery with some circumstances, there are exceptions that we've discussed, right?
MR. RUMANEK: Object to the form.
A We've discussed a lot of things, but in general, it's used less often in primary repair.
Q And --
A Well, it's not available anymore, but --

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Q Sure.
A -- mesh is used less often in primary repair currently.
Q And the circumstances we talked about where it would be appropriate for primary repair is in a patient with decreased tissue quality, right?
MR. RUMANEK: Object to the form. Mischaracterizes the previous testimony.
A That's one of the circumstances.
Q Right. And another circumstance where the use of PROLIFT or mesh-based repair would be appropriate is if they failed a previous surgery, right?
A That is another circumstance, correct.
THE WITNESS: Are we at a point where we can take a break?
MR. BENTLEY: Sure.
(Recess from 11:26 a.m. to 11:29 a.m.)
BY MR. BENTLEY:
Q Doctor, I'm handing you what's being marked as Exhibit 13. This an abstract from Damoiseaux and the International Urogynecologic Journal from 2015; you see that?
(Exhibit 13 was marked for identification.)

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A Yes.
Q Are you familiar with this?
A Not off the top of my head, but --
MR. RUMANEK: Take a second to read it.
Q I'll represent to you that it's included on your reliance list, so presumably you reviewed it at some point in preparing your report; is that correct?
A Correct.
Q And let's just clear up, you actually reviewed all the materials that are listed on your reliance list?
A To some degree.
Q So are there some you didn't review?
A I'm sure there's some I didn't review in detail, correct.
Q Right. And there's a couple of pages of deposition testimony on here. Did you review all of these corporate employee depositions?
A No.
Q Did you review any of them, do you recall?
A Not that I recall.
Q And there's a number of, looks like, internal documents, did you review most of those or do you recall?

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A I did review some of those, correct.
Q You don't know which ones you did, though?
A No.
Q And how did you prepare --
MR. RUMANEK: Were you done answering the question?
THE WITNESS: Yeah, I was done.
Q How did you prepare this reliance list?
A How did I prepare it?
Q Uh-huh.
A Articles were just provided in general. Some were things that I requested. Others were just, you know, mass qualities of articles to put forth, here is what you can review for your report.
Q So you added things to this list as they were given to you?
MR. RUMANEK: Object to the form. I'll just note on the record to clear up any sort of confusion, he didn't actually prepare, but -- he didn't type up --
MR. BENTLEY: For the record, Plaintiffs are going to request that we get an actual reliance list and the materials the doctor reviewed. This is inaccurate and prevents me from having a fair deposition to figure out

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what he actually reviewed and relied upon. So that's another reason we're requesting to keep the deposition open.
MR. RUMANEK: And I'll respectfully --
Q All right. Turning --
MR. RUMANEK: Let me respond to that.
MR. BENTLEY: Respectfully object.
MR. RUMANEK: I disagree with that analysis, and --
MR. BENTLEY: He just testified that he didn't review everything that's on this. And you just testified that -- or you just stated that you prepared this, so it doesn't reflect what he actually reviewed. The record states --
MR. RUMANEK: And he's testified that the materials that are on there were materials that were provided to him, that he looked at in some degree or another.
MR. BENTLEY: The record speaks for itself.
MR. RUMANEK: And --
MR. BENTLEY: We're not going to waste my time.
MR. RUMANEK: I just disagree with your

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objection.
BY MR. BENTLEY:
Q Doctor, turning back to Exhibit, is that 15?
A 13.
Q 13, and Damoiseaux is on your reliance list, and so now do you recall ever looking at this?
A It looks -- off the top of my head, no, I don't remember it exactly.
Q All right. And there is the problem, is I thought you had looked at it.
A It was a large body of --
Q Totally.
A -- of literature there.
Q Right. The title here is --
MR. RUMANEK: Let him finish his answer.
MR. BENTLEY: Well, that wasn't actually a question.
Q The title is Long-term Follow-up, Seven Years Of A Randomized Control Trial, Trocar Guided Mesh Compared With Conventional Vaginal Repair And Recurrent Pelvic Organ Prolapse; do you see that?
A Yes.
Q And you'd agree that seven years is a pretty long-term follow-up of literature, right?

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A In general.
Q That's useful information, right?
MR. RUMANEK: Object to the form.
A Seven years, it's good to know the term of follow-up, correct.
Q And here they're discussing -- on the right side of the page, they state that, "The primary outcome for this long-term follow-up was composite success"; do you see that?
A On the right side of the page? Oh, okay. Primary outcome -- okay.
Q And they define it as "leading edge of pelvic organ prolapse, not outside of the hymen without bulge symptoms or reoperation for prolapse"; do you see that?
A Yes.
Q And would you agree that, I think, they're defining a composite, it next says, "An anatomical measurement plus patient satisfaction to some extent"?
MR. RUMANEK: Object to the form.
A I don't know. Does it define composite index on here?
Q Well, I think it does in the parenthesis. Or how would you --

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A Being edge of prolapse, okay. Okay. Yeah. Yeah.
Q The bold --
A I agree with that.
Q The bold symptoms is probably the patient subjective component of the next -- is that fair?
A I would believe so, correct.
Q And if you turn to the next page, on the left side in the middle of the sentence, they state, "The composite outcomes showed no difference in success rate between trocar guided mesh or conventional surgery using native tissues"; do you see that?
A On the left side, let me see, "No difference in baseline characteristics" -- "equal between both groups", correct. "Composite showed no difference in the success rate between trocar guided mesh or conventional surgery" -- I'm just reading this over for a minute. So the anatomic success rate was higher in the mesh group, particularly significant for the anterior compartment.
Q Which is meaning -- for all fairness, it's consistent with what we looked at in the Cochrane Review, right?
A It didn't specifically state that. It

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didn't specifically look -- I don't remember what --
Q It's all right. This is a seven-year follow-up, right --
A Right.
Q -- using a composite index, which is a combination of some sort of anatomic success plus patient satisfaction, right?
A Correct.
Q And based off of that composite, turning your attention to the conclusions, the authors here conclude that, "Alternative non-mesh treatments, including non-surgical, should seriously be considered," on the bottom of the conclusion; do you see that?
A Let me just read through the whole conclusion for a minute.
Q Okay. Well --
A Found no difference in pain, dyspareunia between the two groups --
Q Doctor, their conclusion here --
A Uh-huh.
Q -- is based off of their data doing seven-year follow-up using a composite index, "Alternative treatments, non mesh, should seriously be considered," that's their conclusion, right?

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MR. RUMANEK: That's one -- object to the form. That's one sentence of the conclusion.
A Yeah, that is one sentence. In the beginning it talks about rates of dyspareunia, didn't -- different between two groups.
MR. BENTLEY: I move to strike and just ask my question again.
Q It's very simple. At the end of the Conclusion section here, the authors conclude -- at the end of this paragraph, the authors state, "Alternative non-mesh treatments including" surgical should seriously -- "including non surgical should seriously be considered." Based off of their seven-year follow-up using a composite index, the authors here have concluded that non-mesh treatment should seriously be considered? That's all I'm asking. That's their conclusion, right?
MR. RUMANEK: Object to the form. Speaks for itself.
A And one sentence of --
Q Great.
A -- of a long conclusion, that is correct.
Q Right. And as you sit here today, do you have any criticism or critique or reason to discount this seven-year follow-up using a composite index

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comparing native tissue repair to PROLIFT?
MR. RUMANEK: Object to the form.
A You know, I have not sat down and read this in detail to give you an answer.
Q Right. But it's on your reliance list, right?
A Well, I've read a thousand --
Q I'm going to hand you what's being marked as Exhibit 14. And this is a study by Stanford, published in 2012; do you see that?
(Exhibit 14 was marked for identification.)
A Yes.
Q Do you -- I'll represent to you that this is on your reliance list. Do you recall reviewing this?
A I don't remember this specifically, but it is on my list.
Q You're not familiar with this study by Stanford?
MR. RUMANEK: Object to the form.
A Not off the top of my head.
Q And this study is titled Traditional Native Tissue Versus Mesh-augmented Pelvic Organ Prolapse Repairs: Providing An Accurate

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Interpretation Of Current Literature; is that correct?
A Correct.
Q And you had testified earlier that you estimate the native tissue repair success -- strike that.
You testified earlier that you think the native tissue failure rate was somewhere around what -- what do you think the native tissue repair rate is?
MR. RUMANEK: Object to the form.
A I understand it's around 30 percent, 30 to 50 percent.
Q Failure. And if you would please turn to page 25 under the Conclusions, the authors begin, "Published success rate when recurrent prolapse is the outcome measure for anterior repair alone is at least 73 percent, taking into consideration all studies. Most, however, show a success rate around 92 percent"; do you see that?
A Yes.
Q And they're just stating here that the evidence for native tissue repair is more favorable than originally it was thought, is that a fair representation?

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MR. RUMANEK: Object to the form.
A It's stating here from their conclusion --
Q Right.
A -- they're stating that as one statistic, but there are plenty of articles in the body of literature that have different numbers.
Q Right.
A This is their conclusion.
Q And if you want to turn back to the first page, you can see how they got to that conclusion. Under the abstract, you can see the second sentence, they state, "A comprehensive literature review was performed using PubMed and bibliography searches to compare the anatomic success rates of native tissue in mesh-augmented prolapse repairs and to analyze outcome measures used to" repair -- "to report success rates"; do you see that?
A Yes.
Q So they did a comprehensive literature review similar to Cochrane, and that's how they reached their conclusion, right?
MR. RUMANEK: Object to the form.
A Yes, that's how they reached their conclusion.
Q And that conclusion's contrary to your

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opinion as to what the failure rate is of native tissue repair, right?
MR. RUMANEK: Object to the form. Mischaracterizes the testimony.
A That conclusion is contrary -- they're citing a lower failure rate than I cite, correct.
Q Much lower --
MR. RUMANEK: Object to the form.
Q -- right?
A What do you define as much?
Q Well, they're --
A They're saying about a 17 percent failure rate and I'm saying --
Q At least 200 percent -- 200 to 300 percent --
A Probably about 100 percent on the low end, yeah.
Q Right. Do you want to update the figures in your report as to what you think their failure rate is of native tissue repair?
MR. RUMANEK: Object to the form.
A No.
Q Do you have any reason to discount or criticize the findings of the Stanford review?
MR. RUMANEK: Object to the form. Object

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to the form.
A I have not had time to go through and read this in detail right now to answer that question.
Q Would you like to have time to go through it and read it in detail?
A Sure.
Q Could that have affected your opinions in your report?
MR. RUMANEK: Object to the form.
A No.
Q Is there any literature out there that could really change your opinions in your report --
MR. RUMANEK: Object to the form.
Q -- at this point?
MR. RUMANEK: Object to the form.
A My opinions are based on the broad scope of literature and personal experience and not one specific article.
Q So is that a no?
MR. RUMANEK: Object to the form.
Q Is there any literature out there that could change your opinions at this point?
A There's -- possibly, but there's no specific articles I'm aware of right now.
Q If articles show that native tissue repair

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was more effective than you've put in your report, would that change your opinions?
MR. RUMANEK: Object to the form.
A I would -- my opinion's based on a combination of literature, discussion with colleagues, personal experience, so I can't tell you there's a specific thing that would change my opinion.
Q Doctor, I'm handing you what's being marked as Exhibit 15. Change the subject a little bit. Is it your opinion that PROLIFT degrades in vivo?
(Exhibit 15 was marked for identification.)
A No, or if it does, I don't believe there's any clinical significance to that.
Q Okay. So which is it, does it degrade or there's no clinical significance because it degrades?
MR. RUMANEK: Object to the form.
A There are articles on both sides of the argument, one saying it degrades, another says it doesn't. A lot of these have to do a lot with the way the material's processed, so it's debatable.
Q So you think that the problem with some of

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the degradation are -- let me rephrase it.
You admit some of the articles do show degradation, right?
MR. RUMANEK: Object to the form.
A They think that they are showing degradation.
Q You agree that there's literature out there on both sides of the debate regarding degradation, right?
A Correct.
Q Right. And your critique or reason to discount some of the articles that show degradation is because during processing, that may have created the appearance of degradation?
MR. RUMANEK: Object to the form. Mischaracterizes the testimony.
A There is one article that specifically discusses processing, correct.
Q And are you familiar with the Iakovlev article that I just handed you?
A Degradation -- it might have been one of the ones that I reviewed.
Q I represent to you it's on your reliance list. Are you familiar with it as you sit here today?

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A Not specifically in detail, correct.
Q And, I mean, to be fair, this is published in the Society for --
A Biomaterials.
Q -- Biomaterials, which is not exactly what you practice in; is that correct?
A I do not specifically practice biomaterials, correct.
Q Right. And it's slightly different than what your day-to-day practice is, right?
MR. RUMANEK: Object to the form.
A It is a journal that I'm not familiar with, correct.
Q And you testified that you don't do microscopic examinations of explanted mesh, right?
A Do not examine things microscopically, correct.
Q Right.
A But I am familiar with, you know, these things as they pertain to what I do.
Q So if you'd turn to page 2, Doctor, on the left side of that first paragraph, it ends -- the second-to-last sentence they stated, "We employed a different methodology by studying cross sections of explanted mesh without its separation from tissues.

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This approach allowed us to avoid possible artifacts associated with tissue removal and enabled side-by-side comparison of degraded and non-degraded polypropylene as well as the surrounding tissue components"; do you see that?
A Yes.
Q And do you understand that these authors tried to look at that very concern that you had with some of the studies showing degradation, they tried to figure out a way to not let processing in any way affect degradation? You understand that?
MR. RUMANEK: Object to the form.
A That was their intent, correct.
Q Right. And based off of that, if you turn back to the abstract, for brevity here, on the right side of the abstract, about halfway through, they state, "Cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation"; do you see that?
A Yes.
Q So these authors attempted to address your concerns, and very rightly, the concerns that maybe the explanting and processing has created degradation, and these authors changed their methodology to try and address that, and based off

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of that, they still concluded that the mesh is degrading; do you see that?
MR. RUMANEK: Object to the form.
A Specifically, let's see, chemical products and degradation would be analyzed and studied for that role. Yeah, they are concluding their findings where they thought that there was some degradation of the mesh based on their technique, correct.
Q Which attempted to address the issues that have been raised, right?
MR. RUMANEK: Object to the form.
Mischaracterizes the evidence.
A Attempts, but is there -- this is just one of many attempts.
Q Correct. And as you sit here today, do you have any criticisms or reasons to discount this study done by Iakovlev?
MR. RUMANEK: Object to the form.
A Well, my objection would be to the actual clinical significance of this.
Q Right. So -- I understand that and we can get that. Do you have any criticisms of this specific piece of evidence --
MR. RUMANEK: Object to the form.
Q -- other than your statement that there's

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no -- you don't think there's clinical significance?
MR. RUMANEK: Object to the form.
A I can't disagree with what they came up with, correct.
Q And regarding clinical significance, you would agree that mesh stiffness does have a clinical outcome, right?
MR. RUMANEK: Object to the form.
A Not necessarily.
Q Different meshes have different outcomes based off of the different mesh properties inherent in the construction, right?
MR. RUMANEK: Object to the form.
A Repeat one more time.
Q Different meshes have different constructions, right?
A Different -- well, different meshes, you're talking about polypropylene here, correct?
Q Sure. All -- the construction of the mesh dictates the pore size, right?
A Correct.
Q And we've discussed the mesh geometry and construction and the knitting process, that dictates the stiffness of the mesh, right?
A It could, correct.

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Q And different stiffness -- meshes with different stiffness act differently, would you agree?
MR. RUMANEK: Object to the form.
A In what way?
Q I mean, it's a different product, it's going to bend differently because it's stiffer, right?
MR. RUMANEK: Object to the form.
A There are different products, but I can't tell you clinically as to what the significance in their difference is.
Q All right. But clearly here the author is finding that degradation is causing stiffness, you'd agree with that?
MR. RUMANEK: Object to the form.
A If that's what they state specifically.
Q Right.
A I think they did state that.
Q Right. He states, "Cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation"; do you see that?
MR. RUMANEK: Object to the form.
A Yes.

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Q So he found that it was just stiffer because it was -- the mesh that had degraded was stiffer, that's just what they found, right?
MR. RUMANEK: Object to the form.
A That's what they found, correct.
Q And he's asserting that a stiffer mesh does have clinical significance, that's his conclusion, right?
MR. RUMANEK: Object to the form.
Mischaracterizes. The evidence speaks for itself.
A I mean, but they don't specifically state what the clinical significance is.
Q Right. But, I mean, that's their conclusion here, though, is that they're --
A Right, it says --
MR. RUMANEK: Hold on. Let him ask the question, you answer the question.
THE WITNESS: Okay.
Q Their conclusion simply, whether or not you agree with it, is that stiffer mesh -- the mesh is stiffer because it's degrading, which has a clinical impact, that's mainly what they found here, right?
MR. RUMANEK: Object to the form. The

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article speaks for itself.
A That's what they stated --
Q Right.
A -- but they didn't state clinically what they're calling a clinical problem.
Q And so my question is, what -- what reason do you have to discount the findings of this article that was -- you reviewed in preparation for your report?
MR. RUMANEK: Object to the form.
A No more than the ones that support that there's no problem.
Q And if mesh degrades and falls apart and gives off particles, you understand that that's one of the theories that happens, whether or not you agree with it, but you understand that's one of the theories, right?
A Yes, correct, it's one of the theories.
Q And if loose particles are released in the body, you understand that that changes the inflammatory response to an implant inside a woman's body, right?
MR. RUMANEK: Object to the form.
A Not necessarily.
Q You think it's a good thing for a product

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to fall apart in someone's body?
MR. RUMANEK: Object to the form. You're arguing with him at this point. That's not even a question.
A I don't know. Clinically speaking, I don't know what difference it makes.
Q You would prefer for a mesh product that's permanently implanted in someone's body not to fall apart; is that -- you can't agree with that?
A If you're trying to treat prolapse, then the intention is to not have it fall apart.
Q Right. And you understand that having more product spread out is increasing the inflammatory response in the body?
MR. RUMANEK: Object to the form.
A Do you have anything specifically that states that?
Q You would disagree with that?
A I don't necessarily agree or disagree. I'm just asking if you have an article that supports that.
MR. BENTLEY: Where are we at?
COURT REPORTER: One minute.
MR. BENTLEY: I'll stop.
MR. RUMANEK: Give me a couple of minutes

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to go over my notes.
Let's go on the record.
CROSS EXAMINATION
BY MR. RUMANEK:
Q Dr. Goldwasser, I'm going to start at the end and then work my way back towards the beginning.
At the end of the examination, Counsel showed you an article by Dr. Iakovlev, which was marked as Plaintiffs' Exhibit 15; do you see that?
A Yes.
Q Dr. Iakovlev and Dr. Guelcher are Plaintiffs' experts in this litigation, are you aware of that?
MR. BENTLEY: Objection to testimony by Counsel.
A No, I was not aware of that.
Q If you'd flip over to the last, or page 11, the Acknowledgments --
A Okay.
Q -- do you see that it notes that, "The authors provided expert opinions for medico-legal cases on matters related to polypropylene mesh"? Do you see that?
A Yes.
Q And did you review in the course -- in

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putting together your report, I believe you testified -- when did you begin reviewing materials to put together your report?
A I believe it was the end of 2016.
Q So approximately four months ago?
A Four or five months, yeah.
Q Do you remember every article that you read in considering the materials in putting together your report?
MR. BENTLEY: Objection. Vague.
A Of course not.
Q Do you recall reviewing articles on the issue of polypropylene degradation that suggested that there is degradation of polypropylene mesh?
MR. BENTLEY: Leading. Vague. Compound.
A Yes.
Q Do you recall reviewing articles on the other side of the issue, as Counsel noted, that suggested that there is no degradation of polypropylene mesh?
A Yes.
MR. BENTLEY: Objection.
Q And did you consider those articles in putting together the opinions set forth in your report?

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A Yes.
Q And with respect to the opinions on degradation, do you hold the opinions set forth in your report to a reasonable degree of medical certainty?
A Yes, I do.
Q Do you have Exhibit 13 in front of you?
A Yes.
Q And this was an article that Counsel showed to you, correct?
A Correct.
Q If you flip over to the second page of the article, do you see that there's a Table 1?
A Table 7 -- Table 1, yes.
Q It says, "Results of seven-year follow-up"?
A Yes.
Q You see that?
A Yes.
Q With respect to the composite success within that table, do you see that overall the composite success as set forth by the authors was 60 percent for mesh, 58 percent for non-mesh, correct?
A Correct.

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Q So while it's close, the success for mesh was, in fact, higher, correct?
A Correct.
Q If you look at the anatomic success, the overall success listed there is 40 percent for mesh, 22 percent for conventional, correct?
A Where you have an anatomic? Oh, okay. Right below. Yes, correct.
Q And I believe you mentioned earlier that the native tissue success rate that you generally provide is between 30 and 50 percent, correct?
A Yeah, the failure rate for native tissue, yeah.
Q So if you look even in the composite success rate at seven years, as noted in the article that Counsel provided to you, the composite success rate for native tissue repair is 58 percent, correct?
A Correct.
Q Looking back at the overall success rate, when you look in the different compartments within the anterior compartment, the authors reflect a success rate of 74 percent in the anatomic success for mesh, correct?
A Correct.

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Q And 31 percent for conventional, correct?
A Correct.
Q And in the posterior they report a success rate of 85 percent for mesh, correct?
A Correct.
Q And 66 percent for non-mesh, correct?
A Correct.
Q In the Conclusion section of this article, Counsel focused on the last sentence of the conclusion, which read, "Alternative non-mesh treatments, including non-surgical, should seriously be considered"; do you see that?
A Correct.
Q Does that conclusion state that mesh procedures should not be performed?
A Not at all.
Q Looking up in the Conclusion, did the -- did the authors of this study determine that there was no difference in pain or dyspareunia between the mesh and non-mesh groups?
A Correct. No difference, correct.
Q Can you go to Exhibit 12, which was the 2016 Cochrane Review, correct?
A Yes.
Q And Counsel noted that you did not cite

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the 2016 Cochrane in the section that was discussing the efficacy of mesh, correct?
MR. BENTLEY: Objection. Improper question.
A Correct.
Q If you turn over to the -- a few pages within the document to the abstract; you see that?
A Yes.
Q At the very bottom of page 1 that really continues on to page 2, there's a section that says Permanent Mesh Versus Native Tissue Repair; do you see that?
A Yes.
Q And if you flip over that page, the first sentence says, "Awareness of prolapse at one to three years was less likely after mesh repair," correct?
A Correct.
Q And the next paragraph, it says, "The rates of repeat surgery for prolapse were lower in the mesh group," correct?
A Correct.
Q It also says that, "There was no evidence of a difference between the groups for rates of repeat surgery for incontinence," correct?

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A Correct.
Q If you look at the next paragraph, it notes, "Recurrent prolapse on examination was less likely after mesh repair," correct?
A Correct.
Q Do those findings in the 2016 Cochrane, are they consistent with and do they support the opinions set forth in the section of your report that discusses the efficacy of mesh-augmented prolapse repair?
MR. BENTLEY: Objection. Vague. Leading. Compound.
A Yes.
Q And are they consistent with the 2013 Cochrane Review that you did cite in your report?
MR. BENTLEY: Same objections.
A Correct.
Q Counsel asked you whether or not you numerically track as part of a database your success rates with respect to native tissue repair, correct?
A Correct.
Q Can you speak to the clinical experience that you have in performing native tissue repairs without relying on a numerical tracking within a database based on your experience?

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MR. BENTLEY: Objection. Vague.
A Yes.
Q And did you incorporate that into the opinions that you formed in this case?
A Yes.
Q Counsel asked you a number of questions regarding whether or not you hold yourself out as an expert in various areas, including design, biomaterials, industry practices, do you recall those -- that set of questions?
A Correct.
Q You are a urogynecologist, correct?
A Correct.
Q Do you hold yourself out to the world as an expert in any field other than urogynecology?
A No.
Q In the course of your training, education, knowledge, your experience as a urogynecologist, do you develop knowledge and expertise in other areas other than just strictly urogynecology?
A Yes.
Q And do you believe to a reasonable degree of certainty that you have the expertise and experience to testify to the opinions that you've set forth in your report?

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MR. BENTLEY: Objection.
A Yes.
Q Do you have expertise as it relates to issues such as design of medical devices, pathology, industry practices, IFUs to give the opinions that you've set forth in your report?
MR. BENTLEY: Vague. Compound.
A Yes.
MR. BENTLEY: Leading.
Q If you could turn to Exhibit 10, which was a Coloplast document with a woman on the front that says Straight Talk. All right. If you'll turn over to page 9 of that exhibit.
A Okay.
Q And Counsel went through the section that was entitled, Are There Any Risks With Mesh, correct?
A Correct.
Q If you look at the second paragraph, the second sentence is -- begins, "Potential complications from mesh surgery may include," and then do you see various risks listed after that?
A Correct.
Q The first one is pain, correct?
A Correct.

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Q Is pain a risk of both mesh surgery and non-mesh surgery?
A Definitely.
Q The next one says "slow healing or non-healing"; do you see that?
A Yes.
Q Is slow healing or non-healing a risk of both mesh surgery -- pelvic organ prolapse surgery involving mesh and pelvic organ prolapse surgery involving non-mesh repairs?
A Correct.
Q Can you have erosion or exposure of suture material into the vagina or adjacent organs with non-mesh surgery?
A Yes.
Q One of the risks listed is nerve injury. Is nerve injury unique to pelvic organ prolapse surgery with mesh?
A Definitely not.
Q And is that a risk of non-mesh repairs as well?
A Yes.
Q Recurrent prolapse is listed as a potential complication; do you see that?
A Yes.

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Q Is recurrent prolapse a risk that's unique to pelvic organ prolapse with mesh?
A No, not at all.
Q And can you have recurrent prolapse with non-mesh repairs as well?
A Definitely.
Q The next risk that's listed is inflammation. In fact, let me just go through to -- in the interest of time, the remaining risks say, "inflammation, adhesion formation, fistula formation, narrowing of the vagina, scarring, pain with intercourse," and let's stop there, pain with intercourse. Are those risks unique to pelvic organ prolapse repairs using mesh?
A Definitely not.
Q And can all of those potential complications be risks of non-mesh repairs as well?
A Yes.
Q And then it lists "mesh contraction." Can you have contraction of tissue or other material -- let me strike that.
If you're doing a non-mesh repair, can you have -- a native tissue -- strike that.
If you are performing a native tissue repair, can you have scarring that results in

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contraction of the implant?
A Yes, that's a normal part of the healing process.
Q And if you're doing a biological graft implant, can you have scarring and contraction of that implant --
A Yes.
Q -- as a result of the procedure?
A Yes.
Q So is contraction a risk that's unique to mesh surgery?
A No.
Q Counsel asked you a number of questions that related to other physicians' knowledge and how their knowledge and experience may compare with your knowledge and experience. Do you recall those questions?
A Yes.
Q As a physician, who has the obligation of making sure that they are adequately trained to form a procedure on a patient?
MR. BENTLEY: Objection.
A The physician.
Q And who has an obli- -- does the physician have an obligation to investigate and be comfortable

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with the technique required in order to perform a procedure?
MR. BENTLEY: Objection.
A Yes.
Q Does -- does a physician also have an obligation to understand the potential risks and complications associated with a procedure or a product that they're going to perform?
MR. BENTLEY: Objection.
A Of course.
Q I'm going to look now at Exhibit 9. And I just want to clarify the record on this. Do you know when this document was created?
A Do I?
Q Exhibit 9.
A Let's see. I'm looking for a date. No, I don't know. Let me -- what -- I don't see any indication on here as to when it was created.
Q Do you know who drafted this document?
A No, I don't.
Q Did -- did you type in the information? Did you create this document?
A No, I did not.
Q Do you know how the information included in this document came to be created?

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A I don't.
Q Counsel asked you some questions that -- I think the words that he used were you noted this, you said this.
MR. BENTLEY: Objection. Ask a question.
Q Did you type any of the information or put this into this document?
A Not at all.
Q There was some questions that were asked about the sentence that says, "from the patient side, it can be noticed from the male side," do you remember those questions?
A From today, correct, yes.
Q Do you recall even communicating that information to anyone?
A I don't.
Q Do you understand the context of what was meant by that sentence right there?
A I don't, not exactly.
Q Do you have any idea whether this is an accurate transcription or summary of any comments that you did make?
MR. BENTLEY: Vague. Calls for speculation. Compound.
A I don't. I've never seen it and -- well,

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don't recall seeing this until you highlighted it today.
Q If you'll look at Exhibit 6, which is another document. It should be over here. You can probably flip through faster than I can.
MR. BENTLEY: What are you looking for?
MR. RUMANEK: Exhibit 6.
Q Here, you can just look at my copy.
MR. BENTLEY: What is it, the questionnaire?
MR. RUMANEK: Yeah, the questionnaire.
BY MR. RUMANEK:
Q The same questions, there's a date at the top that says November 4th, 2010. Do you know who created this document?
A No, I do not.
Q Do you know -- did you create this document?
A No.
Q Did you put the information in this document to put it into the form that it was provided to you by Counsel?
A No, not as far as I recall.
Q Do you know who put that information into the document that was provided to you by -- as

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Plaintiffs' Exhibit 6?
A I don't.
Q Do you know -- do you recall telling anyone from Ethicon the specific reasons that you trim a mesh graft is because it does not lay flat?
A I don't recall that specifically.
Q Do you recall earlier in the deposition being asked about literature on different topics, one of which was literature related to scar plating?
A Correct.
Q At one point you said that you -- let me ask -- strike that.
Did you review and consider literature that related to scarring, contraction, and scar plating with respect to mesh?
A Yes.
Q And I believe at one point you asked to see particular articles that Counsel was referring to, do you recall that?
A Yes.
Q Did Counsel show you any articles --
MR. BENTLEY: Objection.
Q -- in response to that?
MR. BENTLEY: The record speaks for itself. Improper question.

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A No.
Q If Counsel had showed you that, do you feel like you would better be able to answer specific questions about the reliability or any specific information contained within particular studies?
MR. BENTLEY: Objection. Improper hypothetical. Improper question.
A Yes.
Q But you did review and consider information and literature as it relates to scarring, contraction, and scar plating in putting together your opinion?
MR. BENTLEY: Asked and answered. Leading. Compound. Vague.
Q Did you consider --
MR. BENTLEY: Objection.
Q -- literature --
MR. BENTLEY: Same.
Q Did you consider literature that discussed scar plating, scarring, and tissue contraction with respect to mesh implants?
MR. BENTLEY: Same.
A Yes.
Q The opinions that you've given in the

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deposition today, do you hold those opinions to a reasonable degree of medical certainty?
A Yes.
Q And based on the questions that you were asked, the testimony that you've given, do you still hold all the opinions set forth in your report to a reasonable degree of medical certainty?
A Yes.
MR. RUMANEK: That's all the questions I've got.
REDIRECT EXAMINATION
BY MR. BENTLEY:
Q Doctor, on page 3 of your report, you're discussing your mesh database, and you -- at the bottom of the page, second-to-last paragraph on page 3, you note that your database contains over 450 patients to date. Are you saying that -- I just want to be clear, is that -- are you indicating that there's 450 PROLIFT procedures in your database or 450 total procedures?
A Total, total vaginal mesh procedures.
Q As you sit here today, do you know how many PROLIFT procedures your database contains?
A Not off the top of my head.
Q And you don't know how many PROLIFT+M

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procedures?
A Correct.
Q If you'd please turn to page 28, we were discussing degradation and the existence of various studies on both sides of the debate, you remember that?
A Yes.
Q And on page 28, that first full paragraph, you note that you're not aware of any evidence both personally or in the literature that suggests that this substance degrades in the human body. And my question, that's not exactly accurate, is it, because you know that evidence exists on both side of the debate, right?
MR. RUMANEK: Object to the form.
A There is evidence on both sides of the debate, correct.
Q And throughout your report, Doctor, you make statements that certain things are commonly known. And I understand that you're saying every surgeon knows there's complications, right, but do you have -- there's no evidence out there that indicates doctors were polled or a survey was taken to know exactly what each person knows, is there?
MR. RUMANEK: Object to the form.

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A No one did any polling for this.
Q Right.
MR. RUMANEK: I'll -- time's up.
MR. BENTLEY: It's actually not.
Q And one more question, when you're making your opinions on the IFU, just to be clear, those are based upon your own personal observations and your clinical practice, not on Federal regulations, right?
MR. RUMANEK: Object to the form. Mischaracterizes the report.
A Specifically my knowledge of Federal regulations in regards to the IFU?
Q Right.
A I'm really IFU based on my overall knowledge of the product, but not specifically regulation per se.
Q That's fair, okay. And last, you didn't -- your opinion on the warnings and IFU, that's not based upon your review of Ethicon's internal protocols governing what needs to go into a warning, right?
MR. RUMANEK: Object to the form.
A I know there are some, you know, government stipulations as to what should be

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included in an IFU, and it seems like they hit those targets.
Q But your opinions here, though, are based upon your clinical experience, not on the Federal regulations and not upon Ethicon's internal protocols --
MR. RUMANEK: Object to the form. Mischaracterizes the testimony.
Q -- is that correct?
A Well, I've reviewed what's in my reliance list to some degree, some more so than others, and yes, my conclusions are based on what I presented, correct.
Q Right. And I'm just trying to be clear, though, your conclusions regarding the warnings, they're not based upon your review of Ethicon's internal protocols governing the design of warnings?
MR. RUMANEK: Object to the form.
A I don't -- I can't specifically recall their design of warnings.
Q And they're not based upon your review of the entirety of the Federal regulations governing what needs to go in an IFU, right?
MR. RUMANEK: Object to the form.
A I've reviewed some of that, but I'm not --

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the entire regulation, correct.
Q Because it's --
MR. RUMANEK: All right. That's it.
Q Your opinion on the adequacy of the IFU is not based upon the actual full IFU regulations, right?
MR. RUMANEK: Object to the form. Asked and answered. He's answered that question. We're past the three hours. I was giving you some leeway.
Q You can answer it.
MR. RUMANEK: You've said --
MR. BENTLEY: You've talked on my record for --
MR. RUMANEK: -- the last question four times.
MR. BENTLEY: -- minutes upon minutes. The question was not answered. The testimony will clearly speak for itself.
MR. RUMANEK: The testimony will speak for itself.
BY MR. BENTLEY:
Q Doctor, if you can answer the question. Can you answer it?
MR. RUMANEK: He has answered it.

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(Off-the-record discussion.)
BY MR. BENTLEY:
Q Your report indicates that you looked at 801.109(c), and just your opinions on the IFU are not based upon your review of the entire IFU regulations, are they?
MR. RUMANEK: Object to the form.
A Correct.
MR. BENTLEY: Thank you. Doctor, I appreciate your time.
RECROSS EXAMINATION
BY MR. RUMANEK:
Q Dr. Goldwasser, did you review Federal regulations as they relate to warnings and IFUs in putting together your opinions in this case?
A Yes.
Q And did you consider the regulations that you reviewed in forming the opinions related to the IFU for PROLIFT in this case?
MR. BENTLEY: Objection.
A Yes.
FURTHER REDIRECT EXAMINATION
BY MR. BENTLEY:
Q Doctor, in your report --
MR. RUMANEK: We're done. We're done.

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Q -- you cite -- Doctor, in your report --
MR. RUMANEK: We're done. We're done.
Q -- you don't cite to --
MR. RUMANEK: We're done.
Q -- any other regulations -- Doctor, in your report you cite to 21 CFR 801.109(c), do you see that on page 31?
A Yes.
Q Is there any other Federal regulation that you're basing your opinion regarding the adequacy of the IFU? Is there any other regulation that you're using to get to this opinion here?
MR. RUMANEK: Object to the form.
A I reviewed things on my reliance list, and we can go back to that and we can pull specific things, if need be, and I can tell you if I -- you know, what I reviewed and what I didn't.
Q Totally. And I'm just asking -- I'm trying to get what's the basis for your opinions of the adequacy of the IFU and I'm trying to see if there's any Federal regulation other than this one section that's here. Is there anything else that supports your opinion?
MR. RUMANEK: Object to the form.
A I don't recall off the top of my head.

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MR. BENTLEY: Thank you.
(Witness excused.)
(Deposition concluded at 12:19 p.m.)
- - -

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CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF DUVAL)

I, the undersigned authority, certify that STEVEN GOLDWASSER, M.D., personally appeared before me on March 29, 2017, and was duly sworn.

WITNESS my hand and official seal this 7th day of April 2017.

Stephanie Powers Cusimano, RPR, FPR
Notary Public - State of Florida
My Commission No. GG 013532
Expires: August 3, 2020

REPORTER'S CERTIFICATE

STATE OF FLORIDA)
COUNTY OF DUVAL)

I, Stephanie Powers Cusimano, Registered Professional Reporter, Florida Professional Reporter, and Notary Public in and for the State of Florida at Large, hereby certify that I was authorized to and did stenographically report the deposition of STEVEN GOLDWASSER, M.D.; that a review of the transcript was requested; and that the foregoing transcript, pages 1 through 228, is a true record of my stenographic notes.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 7th day of April 2017.

____ _____
Stephanie Powers Cusimano, RPR, FPR, Court Reporter

ERRATA SHEET

STATE OF FLORIDA:
COUNTY OF DUVAL:

I, STEVEN GOLDWASSER, M.D., the undersigned deponent, have this date read the foregoing pages of my deposition, numbered 1 through 228, and with the suggestions noted below, if any, these constitute a true and accurate transcription of my deposition given on the 29th day of March 2017, at the time and place stated therein.

PAGE NUMBER	LINE NUMBER	SUGGESTION/REASON

_____
STEVEN GOLDWASSER, M.D.

LAWYER'S NOTES

PAGE	LINE	